

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry**



**Annual Meeting of the Advisory Committee on
Childhood Lead Poisoning Prevention
November 14-16, 2012
Atlanta, Georgia**

Record of the Proceedings

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ATTACHMENT 1**List of Participants****ACCLPP Members**

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Dr. Sher Lynn Gardner
Mr. Perry Gottesfeld
Dr. Michael Kosnett
Mr. David McCormick*
Ms. Elizabeth McKee-Huger
Dr. Patrick Parsons
Dr. Brenda Reyes
Dr. Megan Sandel
Mr. Dana Williams, Sr.

Ex-Officio Members

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National Institute for Occupational Safety
and Health

Ms. Kalina Duncan (Alternate)
U.S. Department of State

Dr. Warren Friedman
U.S. Department of Housing and Urban
Development

Dr. Kristina Hatlelid
U.S. Consumer Product Safety Commission

Ms. Jacqueline Mosby
U.S. Environmental Protection Agency

Dr. Edward Murray
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Registry

Dr. Walter Rogan
National Institute of Environmental Health
Sciences

Ms. Cynthia Ruff
Centers for Medicare and Medicaid
Services

Dr. Benson Silverman*
Food and Drug Administration

Liaison Members

Mr. Steve Hays
American Industrial Hygiene Association

Dr. Ezatollah Keyvan-Larijani
Council of State and Territorial
Epidemiologists

Ms. Jane Malone
National Center for Healthy Housing

Ms. Ruth Ann Norton
Coalition to End Childhood Lead Poisoning

Dr. George Rodgers, Jr.
American Association of Poison Control
Centers

Dr. Megan Sandel (Alternate)
American Academy of Pediatrics

Dr. Donald Simmons
Association of Public Health Laboratories

Designated Federal Official

Dr. Vikas ("Vik") Kapil
NCEH/ATSDR Chief Medical Officer &
Associate Director for Science
Acting ACCLPP Chair

CDC/NCEH/ATSDR Representatives

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(NCEH/ATSDR Director)

Thomas Sinks
NCEH/ATSDR Deputy Director

Behrooz Behbod
James Bintzler
Mary Jean Brown
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Tonia Burk
William Cibulas
Kimball Credle
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Qaiyim Harris
Lindsey Horton
Carole Hossom
Diane Jackson
Jeffrey Jarrett
Mark Johnson*
Robert Jones
John Kastenbauer
Cory Kokko*
Shirley Little
Sandra Malcom
Jacquelyn Mason
Sarah Merkle
Deborah Millette
Neva Jane Mullinix
Isaac Nwatse
Heather Overman
Jaime Raymond
Helen Rogers
Ken Rosen
Csaba Siffel
Baghua Tao
Jana Telfer
Denise Tevis
Kristen Wallon
LaToria Whitehead

Sharon Williams-Fleetwood

**Guest Presenters and
Members of the Public**

Lucas Andrews
Jones Day

Reva Berman*
Health Canada

Carolyn Grossman
Magellan Biosciences/Mirepoix

Maria Hegstad*
Inside EPA Weekly Report

Barnes Johnson
U.S. Environmental Protection Agency

David Kyle
Battelle

Jessica Ryman
International Lead and Zinc Research
Organization

Robert Funa
Member of the Public

Christopher Saranko
Environmental Planning Specialists, Inc.

*Participation via teleconference

ATTACHMENT 2

Glossary of Acronyms

ABLES	Adult Blood Lead Epidemiology and Surveillance
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ADHD	Attention Deficit Hyperactivity Disorder
APHL	Association of Public Health Laboratories
BLLs	Blood Lead Levels
CDC	Centers for Disease Control and Prevention
CEC	Commission for Environmental Cooperation
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CLIAC	Clinical Laboratory Improvement Advisory Committee
CLPPPs	Childhood Lead Poisoning Prevention Programs
CMS	Centers for Medicare and Medicaid Services
CoAgs	Cooperative Agreements
COFs	Child-Occupied Facilities
CPSC	U.S. Consumer Product Safety Commission
DFO	Designated Federal Official
DLL	Dust Lead Level
DOS	Department of State
EBLLs	Elevated Blood Lead Levels
ECE	Early Childhood Education
EEHS	Division of Emergency and Environmental Health Sciences
EH	Environmental Health
EIBLL	Environmental Intervention Blood Lead Level
EIP	Early Intervention Program
EIS	Early Intervention Services
EIWG	Educational Intervention Workgroup
EPA	U.S. Environmental Protection Agency
EPSDT	Early Periodic Screening, Diagnosis and Treatment
ETV	Environmental Testing Verification
FAC	Federal Advisory Committee
FDA	Food and Drug Administration
FOAs	Funding Opportunity Announcements
GAELP	Global Alliance to Eliminate Lead Paint
HEDIS	Healthcare Effectiveness Data and Information Set
HHLPPB	Healthy Homes/Lead Poisoning Prevention Branch
HHLPPP	Healthy Homes/Lead Poisoning Prevention Program
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development
ICCM	International Conference on Chemical Management
IDEA	Individual with Disabilities Education Act
IEUBK	Integrated Exposure Uptake and Biokinetic (Model)

IHD	Ischaemic Heart Disease
IPM	Integrated Pest Management
IRATB	Inorganic and Radiation Analytical Toxicology Branch
LAMP	Lead and Multi-element Proficiency
LBP	Lead-Based Paint
LBW	Low Birth Weight
LDR	Lead Disclosure Rule
LHCP	Lead Hazard Control Program
LOC	Level of Concern
LPP	Lead Poisoning Prevention
LSHR	Lead Safe Housing Rule
LSWP	Lead Safe Work Practices
LWG	Laboratory Workgroup
MASO	Management Services and Analysis Office
MMWR	<i>Morbidity and Mortality Weekly Report</i>
NCEH/ATSDR	National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry
NHANES	National Health and Nutritional Examination Survey
NHB	Non-Hispanic Black
NHW	Non-Hispanic White
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NPL	National Priorities List
NPS	U.S. National Park Service
NTP	National Toxicology Program
OJT	On-the-Job Training
OKI	Occupational Knowledge Institute
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OSWER	Office of Solid Waste and Emergency Response
PHAs	Public Health Assessments
POC	Point of Care
PRE	Pre-Renovation Education
RePORTER	Research Portfolio Online Reporting Tools
RRP	Renovation, Repair and Painting
RSV	Respiratory Syncytial Virus
RVBL	Reference Value Blood Lead Level
SHS	Second-Hand Smoke
SIDS	Sudden Infant Death Syndrome
USP	U.S. Pharmacopeia
VOC	Volatile Organic Compound
WHO	World Health Organization
XRF	X-Ray Fluorescence

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**ANNUAL MEETING OF THE ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
November 14-16, 2012
Atlanta, Georgia**

Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened the annual meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on November 14-16, 2012 in Building 106 of the CDC Chamblee Campus in Atlanta, Georgia.

Opening Session: November 14, 2012

Vikas (“Vik”) Kapil, DO, MPH, FACPOEM

Chief Medical Officer and Associate Director for Science, NCEH/ATSDR
Centers for Disease Control and Prevention
Acting ACCLPP Chair and Designated Federal Official

Dr. Kapil opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. He confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 14, 2012. He called the proceedings to order at 9:09 a.m. and welcomed the participants to the meeting. The list of participants is appended to the minutes as Attachment 1.

Dr. Kapil reminded the ACCLPP voting members of their individual responsibility to identify real or perceived conflicts of interest with any of the published agenda items and recuse themselves from participating in these matters. None of the ACCLPP voting members disclosed any conflicts of interest for the record.

Dr. Kapil announced that in addition to his duties as the Designated Federal Official (DFO), he also would serve as the Acting Chair during the meeting. However, Dr. Deborah Cory-Slechta, an ACCLPP member, would moderate discussions for the scientific presentations and workgroup reports. Dr. Kapil noted that the new ACCLPP Chair and members would be officially appointed after the Office of the HHS Secretary completes its review and formally approves the nomination packages.

Thomas Sinks, PhD

Deputy Director, CDC National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry

Dr. Sinks also extended his welcome to the ACCLPP meeting. He asked the participants to join him in acknowledging the outstanding leadership, expertise and skills that Dr. Mary Jean Brown, Lead Scientist of the CDC Healthy Homes/Lead Poisoning Prevention Program (HHLPPP), has brought to bear to advance lead poisoning prevention (LPP) for the nation.

In addition to its internal LPP assets, Dr. Sinks also recognized the tremendous level of external expertise by CDC's federal partners that serve on ACCLPP as *ex-officio* members. Public health accomplishments in lead have outnumbered those of any other environmental health (EH) issue in the United States.

Most notably, public health capacity to measure childhood blood lead levels (BLLs) has resulted in a significant decline nationally. However, the large number of federal partners that serve on ACCLPP as *ex-officio* members emphasize the importance of and critical need to continue to prevent exposures by focusing on lead in air, water, food, consumer products and workplaces.

In addition to surveillance and other public health components, LPP also is an important issue in housing and clinical medicine (e.g., screening of children and case management). Dr. Sinks commended ACCLPP on its long and rich history of developing solid LPP guidance for public health, housing and clinical practice across the country.

Dr. Sinks highlighted two of ACCLPP's most recent milestones. The *CDC Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women* have been an extremely important and influential document for clinicians in the field. The ACCLPP Report, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*, has presented multiple opportunities and challenges for CDC in implementing the recommendations due to severe budget cuts.

Dr. Sinks announced that management and oversight of ACCLPP were relocated from the NCEH Healthy Homes/Lead Poisoning Prevention Branch (HHLPPB) to the NCEH/ATSDR Office of Science. The relocation is expected to increase the efficiency and cost-effectiveness of administrative functions, but the NCEH Division of Emergency and Environmental Health Services (EEHS) will continue to provide ACCLPP with technical assistance, subject-matter expertise and scientific support.

Dr. Sinks concluded his opening remarks by thanking ACCLPP for continuing to contribute its valuable time, expertise and support to help CDC in further advancing LPP for the nation.

Sharunda Buchanan, PhD, MS

Director, Division of Emergency and Environmental Health Services
Centers for Disease Control and Prevention

Dr. Buchanan joined her colleagues in welcoming the participants to the ACCLPP meeting. She was privileged and honored to have established and maintained long and productive working relationships with Dr. Brown and most of the federal partners that serve as ACCLPP *ex-officio* members.

Dr. Buchanan commended ACCLPP on its tireless and longstanding efforts in preventing and diminishing elevated BLLs (EBLLs) in children throughout the country. She confirmed that CDC has greatly benefited from and would continue to embrace ACCLPP's solid recommendations.

Status Report on CDC's Childhood Lead Poisoning Prevention Programs

Mary Jean Brown, ScD

Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Brown presented a status report on CDC's 35 childhood lead poisoning prevention programs (CLPPPs). CDC funding of state and local CLPPPs ended on September 1, 2012 and resulted in a cut of ~\$19.8 million to 35 state and local health departments (or ~\$600,000 per grantee). CDC funding supported ~170 HHLPP positions at state and local levels that were necessary for a diverse range of activities: epidemiology, surveillance of childhood BLLs in the United States, health education to providers and the public, program management, case management, information technology, and data entry/clerical functions.

CDC reviewed 27 of the 35 funded states in September 2012 and granted no-cost extensions of 3-9 months to 24 states to complete existing activities, particularly the development of a healthy homes strategic plan. Programs are implementing multiple strategies to respond to the severe funding shortfalls (e.g., combining activities with other internal programs and providing limited services; seeking reimbursement from Medicaid and other funding sources; concentrating on very limited LPP activities; and relying on foundations and other outside partners for program components).

CDC's review also showed that 13 programs reported a loss of jobs for 44 staff. Most programs achieved reductions by contract cancellations or attrition. Staff loss was reported in all program areas, but epidemiology and data entry functions were most severely impacted. To date, five programs have made commitments to continue to report surveillance data to CDC after their no-

cost extensions end, but CDC expects that some of the remaining 30 programs also will submit data.

CDC identified a number of developing and anticipated external impacts due to the elimination of LPP funding. The concept of statewide comprehensive programs to address all health hazards in the home will be lost. The merger of program management functions with other programs will result in a dilution of effort. Education and outreach programs will be drastically reduced. For example, CDC's presence at LEAD WEEK 2012 was minimal compared to previous years. Healthcare provider education and consultation will be discontinued.

Surveillance capacity will be reduced due to the loss of epidemiology staff. Case management capacity will be reduced due to longer wait times for environmental inspections and less ability to make follow-up contact with families. Program effectiveness will be reduced due to the elimination of program evaluation. State funding to local programs for inspections, home visits and health education will be eliminated. State programs that fully depended on CDC funding will be eliminated.

Elimination of LPP funding also has resulted in internal impacts, particularly the reduction in the workforce from 28 staff to 4 scientists and 2 public health advisors. The remaining 6 staff will provide LPP expertise and analysis required by FY2012 Congressional appropriations language. These activities include continued support for ACCLPP, surveillance, policy development, and limited epidemiological responses to lead issues or outbreaks in the field. HHLPPB was pleased that elimination of LPP funding did not result in any staff job losses. The other 22 staff members were deployed to other parts of CDC.

The following internal activities have been entirely eliminated from CDC's LPP portfolio:

- support for public health professionals to participate in LPP training through the Healthy Homes Training Center and Network;
- implementation of health education campaigns;
- program evaluations;
- management of cooperative agreements (CoAgs); and
- participation in conferences, meetings or expert consultation to state and local decision-makers. However, CDC will attend these events if the requesting agency funds CDC's travel.

Drs. Brown and Warren Friedman, the ACCLPP *ex-officio* member for the U.S. Department of Housing and Urban Development (HUD), described the continued importance of lead in the decision-making process for HUD grants. Health departments that demonstrate collaboration with state and local LPP programs receive higher scores on their competitive grant applications to HUD.

In the competitive application process for grants under HUD's new "Safe and Healthy Housing Investment Partnerships Certification Program," applicants that demonstrate integrated public/

private partnerships with local health and housing agencies will receive bonus points. Dr. Brown hoped that the incentive of higher scores on HUD grant applications would encourage states to continue to collect and report lead surveillance data to CDC.

Dr. Kapil moderated ACCLPP's discussion with Dr. Brown on the status of CDC's 35 CLPPPs. The discussion topics included:

- differences between National Health and Nutrition Examination Survey (NHANES) data (e.g., a representative sample of the non-institutionalized U.S. population) and lead surveillance data reported to CDC by states (e.g., BLLs of actual children);
- uncertainty regarding CDC's ability to continue to support laboratory activities in the field, particularly quality assurance practices for blood lead measurements, due to the elimination of the \$1 million Congressional line-item for the CDC laboratory;
- the possibility of states changing existing LPP policies due to the loss of funding;
- potential reasons for the 40% of U.S. children with BLLs $>5 \mu\text{g/dL}$ who are not identified and screened for lead (e.g., residence in low-income neighborhoods with poorly maintained rental properties, residence in middle/upper class homes that are renovated, or persistent inability to access the healthcare system); and
- concerns and fear among parents of being unable to secure medical, educational or mental health services for their lead-poisoned children at the local level due to the loss of LPP funding at the federal level.

Dr. Robert Jones, Chief of the CDC Inorganic and Radiation Analytical Toxicology Branch (IRATB), responded to ACCLPP's comments regarding the impact of the loss of LPP funding on laboratory activities in the field. IRATB is responsible for generating CDC's LPP data, but its budget was completely eliminated. Due to IRATB's critical public health role, however, EEHS secured funds from other sources and restored ~50% of the IRATB budget for continued support of the laboratory component of LPP activities.

Dr. Jones was pleased that the funds allowed IRATB to maintain staff to continue to generate data and develop laboratory methods, but the loss of 50% of the laboratory budget will have serious implications in the future. Beginning in 2013, for example, IRATB will use a half subset of NHANES data for children ≥ 12 years of age instead of the full subset of 5,000 children with blood lead tests. However, the full NHANES subset of children 1-11 years of age will continue to be used due to the critical need for childhood blood lead data in developing statistics for younger age groups.

The contract to provide IRATB with filter paper for the Lead and Multi-element Proficiency (LAMP) Program will be eliminated. IRATB will perform a budget analysis each year to determine whether funds are sufficient to continue to support the remaining LAMP components, particularly quality control/quality assurance programs for overseas laboratories. EEHS is now supporting service contracts due to the elimination of the Congressional line-item. Less funding will be allocated to the replacement of old laboratory equipment and supplies.

Mr. Jeffrey Jarrett, a Research Chemist in the CDC Division of Laboratory Sciences, has provided the ACCLPP Laboratory Workgroup with extensive support and technical expertise. He noted that his participation in these activities will be limited in the future. IRATB's funding and support to conduct laboratory studies on lead will be reduced, including research on the LeadCare II instrument and blood lead reference materials.

ACCLPP was extremely disheartened by the severe consequences of the loss of LPP funding and services, particularly decreased opportunities for children to receive case management, medical care and educational services to recover from lead exposures. The members made comments and suggestions in two areas to address this issue.

- CDC should perform an analysis to determine the actual impact of the loss of LPP funding on state and local infrastructures beyond the 35 CLPPPs. For example, city programs, nonprofit organizations and other groups that depended on CDC funding through state and local CLPPPs will no longer be able to conduct business.
- ACCLPP should send a letter to the HHS Secretary and CDC Director to express concerns regarding the loss of LPP funding, describe adverse impacts to children, highlight projected economic outcomes if LPP funding is not allocated, and request restoration of the LPP budget. ACCLPP's December 2, 2011 letter to the HHS Secretary should serve as the basis of drafting the new letter, but other important issues should be addressed as well.
 - A case study should be included. For example, Baltimore complied with ACCLPP's recommendations to focus on primary prevention and lower the threshold for intervention. As a result, the number of childhood lead poisoning cases in Baltimore has dramatically increased.
 - The economic impact for states to implement the new ACCLPP recommendations on low-level lead exposures should be articulated.
 - Other ongoing national efforts should be highlighted. For example, the U.S. Conference of Mayors engaged the HHS Secretary and Congress in its recent resolution to increase the LPP budget to \$50 million to fund both states and the top 10 cities with the highest number of childhood lead poisoning cases. The resolution will be submitted to the White House.
 - The need for Maryland, Rhode Island and other states to divert portions of their budgets from other areas (e.g., inspections and primary prevention) to cover the loss of LPP funding from CDC should be emphasized.
 - Solid data should be cited (e.g., studies demonstrating the impact of BLLs on grade-level reading and learning, HUD data on investments in primary prevention, HUD's reliance on CDC's lead surveillance data to improve its housing programs, and data on the economic benefits of LPP).

In response to the suggestion for ACCLPP to send a letter to the HHS Secretary and CDC Director on the loss of LPP funding, Dr. Brown summarized ACCLPP's duties as outlined in its charter: (1) provide advice and guidance on new scientific knowledge, technological developments and practical implications for childhood LPP efforts and (2) review and regularly

report on prevention practices and recommend improvements in national childhood LPP efforts. Dr. Brown pointed out that ACCLPP's guidance on the LPP budget would be beyond the scope of the charter.

Dr. Sinks encouraged ACCLPP to convey constructive messages in the letter by describing the components of a "solid," "ideal" and "functional" LPP program that are necessary to protect children in the United States. He cautioned ACCLPP against discussing the LPP budget in the letter.

Several members emphasized that guidance to the HHS Secretary and CDC Director to sustain LPP programs with adequate funding and support would be consistent with the language in the charter for ACCLPP to provide advice on new scientific knowledge and recommend improvements in national childhood LPP efforts. Agreement was reached for ACCLPP to draft the letter to the HHS Secretary and CDC Director. The discussion was closed with a summary of next steps in this effort.

1. Drs. Kim Dietrich, Michael Kosnett and Brenda Reyes will draft the letter that will be presented for ACCLPP's review, discussion, revision and formal vote during the business session on November 16, 2012.
2. Dr. Brown will circulate ACCLPP's December 2, 2011 letter to the HHS Secretary.
3. Mr. John Kastenbauer is Chief of the Federal Advisory Committee Management Branch in the CDC Management Services and Analysis Office (MASO). He will attend the meeting on the following day to provide guidance and answer questions by the members on ACCLPP's charter.

Update on the CDC Healthy Homes/Lead Poisoning Branch

Mary Jean Brown, ScD

Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Brown presented an update on HHLPPB's recent activities. HHLPPB published 4 peer-reviewed papers in scientific journals and 4 non-peer-reviewed papers in the *Morbidity and Mortality Weekly Report (MMWR)* or on the CDC.gov website in 2011-2012:

1. "Lead Poisoning Among Burmese Refugee Children: Indiana, 2009"
2. "Lead Poisoning in United States-Bound Refugee Children: Thailand-Burma Border, 2009"
3. "Outbreak of Fatal Childhood Lead Poisoning Related to Artisanal Gold Mining in Northwestern Nigeria, 2010"
4. "Childhood Lead Poisoning Associated with Gold Ore Processing: A Village-Level Investigation-Zamfara State, Nigeria, October-November 2010"

5. "Lead Poisoning in Five Pregnant Women Associated with the Use of Ayurvedic Medicines from India, 2011-2012"
6. "Infant Lead Poisoning Associated with Use of Tiro, an Eye Cosmetic from Nigeria-Boston, Massachusetts, 2011"
7. "Lead in Water and Human Blood Lead Levels"
8. "CDC Using Health Data to Highlight Milestones: A Cookbook for Non-Profit Program Managers"

Dr. Brown provided additional details on one of the non-peer-reviewed publications, but she noted that the slides contained full citations for all 8 publications. The Cookbook presents data from the United States, Georgia, Fulton County, Atlanta and Atlanta Neighborhood Planning Unit-V as examples of comparisons of morbidity and mortality across different geographic areas. However, most of these data sets are available in other areas of the country.

The Cookbook demonstrates the impact of programs by describing surveillance systems for EBLLs, asthma and home injuries and by discussing overlapping risk factors that result in housing-related health disparities. Cookbook data can assist program managers in creating evaluation plans for green and healthy homes interventions for their organizations. Dr. Brown presented graphs to illustrate the uses of Cookbook data, such as identifying age of housing in different geographic areas to determine risk factors for lead and asthma hospitalizations by age group. The Cookbook is available at www.cdc.gov/healthyhomes/training.html.

HHLPPB will publish an *MMWR* article on November 30, 2012 on its Epi-Aid in response to environmental exposures from lead among children of employees of a battery recycling facility in Puerto Rico. From November 2010 to May 2011, 4 voluntary blood lead screening clinics performed blood lead testing on 227 persons from 78 families. Among 67 children <6 years of age, 16% had confirmed BLLs ≥ 10 $\mu\text{g}/\text{dL}$ and 52% had venous or capillary BLLs ≥ 5 $\mu\text{g}/\text{dL}$.

The overarching purpose of the Epi-Aid was to establish whether take-home lead exposure contributed to children's BLLs ≥ 10 $\mu\text{g}/\text{dL}$. Investigators collected and analyzed household environmental samples for lead. As of October 30, 2012, 188 homes and 268 vehicles of current and former employees were sampled. Of initial vehicle dust samples, 85% exceeded the EPA cleanup dust lead level (DLL) for household floor samples of 40 $\mu\text{g}/\text{ft}^2$.

Of home dust samples, 49% exceeded the EPA cleanup DLL for household floor samples of 40 $\mu\text{g}/\text{ft}^2$. A comparison was made between the mean DLL in 18 households with 24 children <6 years of age with BLLs ≥ 5 $\mu\text{g}/\text{dL}$ and 16 households with 18 children <6 years of age with BLLs <5 $\mu\text{g}/\text{dL}$. The mean DLL in 18 households with 24 children <6 years of age with BLLs ≥ 5 $\mu\text{g}/\text{dL}$ was significantly higher (179.2 $\mu\text{g}/\text{m}^2$) than the 16 households with 18 children <6 years of age with BLLs <5 $\mu\text{g}/\text{dL}$ (48.6 $\mu\text{g}/\text{m}^2$).

To date, the U.S. Environmental Protection Agency (EPA) has decontaminated 78% of homes and 55% of vehicles. CDC assigned a case manager to provide education, environmental follow-up and case management for all children with BLLs ≥ 5 $\mu\text{g}/\text{dL}$. On average, children's BLLs have decreased to 9.9 $\mu\text{g}/\text{dL}$ since being enrolled in case management.

The percentage of children <6 years of age with BLLs ≥ 10 $\mu\text{g/dL}$ in the Puerto Rico community was markedly higher than that found during a 2010 population-based, cross-sectional blood lead prevalence study. In the 2010 study, blood lead testing on 440 children <7 years of age detected only 0.7% with BLLs ≥ 10 $\mu\text{g/dL}$.

HHLPPB submitted a paper to the *MMWR* that is currently undergoing the clearance process. The paper analyzes current BLLs in the United States and historical trends. The paper emphasizes that the reference value of ≥ 5 $\mu\text{g/dL}$ defines a high BLL and the inclusion of data on the proportion of children with BLLs ≥ 10 $\mu\text{g/dL}$ is for historical comparisons only. Geometric mean BLLs for children 1-5 years of age and 95% confidence intervals are calculated as well. The paper presents data in four-year aggregates with comparisons of the 1999-2002, 2003-2006 and 2007-2010 NHANES.

The paper focuses on several demographic characteristics that have resulted in longstanding disparities in risk for high BLLs among certain groups by age, gender, Medicaid status, income-to-poverty ratio, and race/ethnicity (e.g., non-Hispanic white (NHW), non-Hispanic black (NHB), Mexican American and other). The income-to-poverty ratio is calculated by dividing the household income by the poverty level as determined by the U.S. Census Bureau and categorized as <1.3 times or ≥ 1.3 times the poverty level.

The data show reductions over time in the percent of children 1-5 years of age with BLLs ≥ 5 $\mu\text{g/dL}$: 8.65% in the 1999-2002 NHANES, 4.11% in the 2003-2006 NHANES, and 2.64% in the 2007-2010 NHANES. The paper includes a standard error of $\geq 30\%$ for estimates that are statistically unstable.

HHLPPB proposes to focus on the geometric mean BLL to meet the *Healthy People 2020* objective of eliminating EBLLs in U.S. children. This method will allow HHLPPB to achieve more stable statistics and place more emphasis on disparities in BLLs. The geometric mean BLL of children reported in the 2007-2010 NHANES was 1.77 in NHBs, 1.28 in Mexican Americans, and 1.26 in NHWs. In addition to race/ethnicity, statistically significant disparities also were observed by income and age of housing.

HHLPPB is conducting a HUD-funded study to measure the cost, benefits and impact of green housing environments on health. The study includes an analysis of multiple green criteria: optimized heating, ventilation and air conditioning systems, recycled building materials, energy-efficient appliances, low/no volatile organic compound (VOC) carpets and paint, integrated pest management (IPM), and improved insulation.

HHLPPB is focusing on four green criteria (e.g., IPM, low VOC materials, insulation and ventilation) as green housing strategies for asthma. These strategies will result in less pests, indoor chemicals and mold growth that will lead to decreased respiratory inflammation and asthma morbidity. The economic outcomes of reduced asthma morbidity will include fewer emergency department visits, fewer hospitalizations, less acute medication use, and fewer missed school days and work days.

The study is designed to determine whether green rehabilitation with multiple strategies lowers medical costs and results in increased productivity among children and their families residing in large publicly-owned housing developments. The environmental sampling component includes vacuum dust sampling to identify allergens and fungi, wipe samples from the kitchen floor to identify pesticides, and passive air diffusion badges to measure VOCs. Novel and traditional air sampling methods are being compared as well.

The green renovation component includes data collection before the unit is rehabilitated and 0, 6 and 12 months after the family returns to the rehabilitated unit. The crossover study design includes both intervention and control groups. The clinical component includes a comprehensive series of measurements among children with asthma 7-12 years of age: blood lead, urine, pulmonary function testing, exhaled nitric oxide, respiratory symptoms, and cold/influenza nasal swabs. Parents will have the ability to send text messages to principal investigators about cold/influenza symptoms of their children throughout the study period.

To date, ~120 families have been enrolled in the study at the Boston and Cincinnati sites. Efforts are underway to secure EPA funding to support the addition of a West Coast site in 2013 that would measure dust intake in children <7 years of age. HHLPPB plans to present preliminary results of the study during the 2013 ACCLPP meeting.

Dr. Kapil moderated ACCLPP's discussion with Dr. Brown on HHLPPB's recent activities. The discussion topics included:

- the omission of Hispanic groups other than Mexican Americans in NHANES samples;
- future plans to measure cytokines and perform a leukocytes challenge in the green rehabilitation study; and
- the possibility of comparing green strategies and less expensive, traditional non-green technologies to determine differences in their health benefits.

ACCLPP advised CDC to provide EPA with its data from both the Epi-Aid in Puerto Rico and the 2010 population-based, cross-sectional blood lead prevalence study. The members pointed out that these data would inform EPA's ongoing decision-making process of revising the residential lead hazard standard.

Overview of the Chicago Childhood Lead Poisoning Prevention Program

Kimball Credle

Public Health Advisor, Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Mr. Credle presented an overview of the Chicago CLPPP's Early Intervention Program (EIP). Chicago has been one of the top 5 cities with childhood EBLs over the past 10 years. To

address this public health issue, the Chicago CLPPP assessed the EIP to determine whether home visits by nurses for children <12 months of age with BLLs 6-9 µg/dL changed the expected course of lead exposure.

The Chicago CLPPP's previous resources included CDC funding of \$1.2 million, HUD funding of ~\$1.2 million, and a staff of home inspectors, case management workers and risk assessors. Due to the loss of CDC funding, the Chicago CLPPP workforce was dramatically reduced from >40 to <10 staff. Moreover, the Chicago CLPPP no longer has adequate funding to sustain its prevention goals and objectives or sufficiently address health disparities. African Americans and Hispanics account for ~95% of the Chicago CLPPP's patient population.

The Chicago CLPPP initiated EIP in 2003 to reduce the incidence of BLLs 5-9 µg/dL among high-risk infants 6-9 months of age. Community health nurses conducted home visits to achieve three major objectives: (1) conduct a visual assessment to control or eliminate lead paint hazards; (2) evaluate other sources of lead, including water, soil, imported products and take-home exposures; and (3) make referrals to the Women, Infants and Children Program and follow-up blood lead testing.

The screening protocol included recommended blood lead testing at 6 or 9 months of age, approximately every 6 months until the child reached 3 years of age, and annually until the child reached 6 years of age. The screening protocol exceeded CDC's current requirements and recommendations.

The objectives of the EIP assessment were three-fold. Adherence to the CLPPP's existing protocol would be measured. Program effectiveness in reducing the number of "high-risk" children 6-12 months of age whose BLLs potentially could increase to ≥ 10 µg/dL by 24 months of age would be examined. Program effectiveness in reducing the number of homes with lead hazards would be examined.

A logic model was developed with several inputs (e.g., screening results, diagnostic laboratory data and state health department data) to guide the EIP assessment. The inputs led to several activities (e.g., case management, blood lead monitoring and environmental risk assessment). The inputs and activities led to several outputs (e.g., percentage and number of initial home inspections, mitigation orders, attempted or completed home visits, follow-up blood lead testing performed within 3 months, and identification of lead hazards). The outcomes were assessed to determine whether the three objectives were achieved.

Preliminary results of the EIP assessment are highlighted as follows. The study population included 1,774 children enrolled in the Chicago CLPPP in 2003-2010. Of the entire cohort, 1,578 had BLLs 6-9 µg/dL and another BLL drawn at least 90 days following the home visit. A significant reduction in BLLs from ≥ 7 µg/dL to 5 µg/dL was observed in enrolled children. Of the enrolled children, 50% were retested within 6 months of their initial test; 75% were retested within 9 months of their initial test; and 90% were retested within 12 months. Of 1,578 children with a retest at least 90 days after the home visit, only 5% had BLLs ≥ 10 µg/dL at follow-up.

Findings of the EIP assessment demonstrate that programs with the capacity to immediately conduct home visits will have a significant impact on reducing the number of childhood blood lead cases. The next steps will be for CDC and the Chicago CLPPP to continue collaborating on redesigning the EIP assessment as a cohort study with a control group.

The study will be designed to evaluate whether other factors (e.g., age, gender and neighborhood) play a role in the correlation between the decline in BLLs and home visits. An analysis will be performed to examine whether other factors can help to identify specific children whose BLLs increase to ≥ 10 $\mu\text{g/dL}$. Environmental lead samples will be included in the study. Overall, children enrolled in EIP experienced a decrease in BLLs. Historically, children's BLLs tend to peak at 12-24 months of age.

ACCLPP was extremely impressed by the preliminary findings of the EIP assessment. The members pointed out that the results demonstrate the effectiveness of prevention, particularly for low-level lead exposures. Several members were in favor of citing these data in ACCLPP's new letter to the HHS Secretary and CDC Director.

Overview of CDC's Study on the Public Health and Economic Burden of Secondhand Smoke in Public Housing

Jacquelyn Mason, PhD

Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Mason presented an overview of an analysis that CDC conducted to determine the public health and economic burden of secondhand smoke (SHS) in public housing. HHS data show that ~25% of children 3-11 years of age are exposed to SHS in their homes. The U.S. Surgeon General issued a report in 2006 that stated tobacco smoke affects every organ in the body. More recent data show that lower socioeconomic status is associated with higher smoking prevalence in vulnerable populations. Young children and elderly persons may be particularly vulnerable to the harmful effects of SHS exposures in the home.

Previous studies have reported that because cigarette smoke migrates between units in multi-family housing, persons in non-smoking households in multi-family housing complexes can be exposed to SHS in their home. HUD data show that 88% of public housing is multi-family. In 2009, HUD recommended a smoke-free policy in public housing.

The World Health Organization (WHO) issued a report in 2010 that described a methodology to assess the burden of disease caused by SHS exposures. CDC used the WHO report as the framework for its study. The WHO report highlighted multiple health outcomes with sufficient evidence of a causal relationship with SHS exposures in adults: lung cancer, ischaemic heart disease (IHD), and the onset or exacerbation of asthma.

The WHO report also described multiple health outcomes with sufficient evidence of a causal relationship with SHS exposures in infants and children: low birth weight (LBW), Sudden Infant Death Syndrome (SIDS), lower respiratory infections, acute or recurrent otitis media, and the onset of asthma.

The overarching objective of the CDC study was to estimate the public health and economic burden associated with SHS exposure in “never smokers” residing in public housing. CDC used published data from the literature and existing databases. CDC began the analysis with HUD data on the entire public housing population and then used data from NHANES and several other sources to refine the study population (i.e., never smokers who live in public housing; the number of never smokers in public housing with the health outcomes of interest; and of these, the number with health outcomes attributable to SHS). For purposes of the study, “never smokers” were defined as persons with blood cotinine levels 0.015-10 ng/mL.

To determine the economic burden, a societal perspective was used, i.e. significant costs were included in the analysis regardless of the payer. Incremental costs which are the excess costs associated with the treatment of people with a disease or health condition as compared with similar people with no diagnosis of a disease or health condition were calculated. The total economic burden was estimated by adding direct medical costs, productivity losses, and direct non-medical costs. All costs included in the analysis were updated to reflect 2011 dollars.

CDC acknowledged several limitations of its study. An assumption was made that the national disease and death rates and cost estimates were applicable to public housing residents. An assumption was made that relative risks for morbidity and mortality were equivalent. All never smokers who met the criteria were included in the study regardless of where their SHS exposure occurred. Blood cotinine levels only reflect recent exposures to cigarette smoke. The analysis did not account for all societal costs and did not include former or current smokers.

Key findings of the study are highlighted as follows. The analysis to determine the public health burden of SHS in adults was based on HUD data that showed ~1.3 million adults ≥ 18 years of age resided in public housing, including 544,689 adults >50 years of age. The analysis showed that 23,706 adults had health outcomes attributable to SHS in public housing in 2011: 17 with lung cancer morbidity, 15 with lung cancer mortality, 371 with IHD morbidity, 161 with IHD mortality, 23,138 with asthma morbidity, and 4 with asthma mortality.

The analysis to determine the public health burden of SHS in infants and children 0-17 years of age residing in public housing was based on HUD data. Depending on the health outcome, this analysis was conducted for specific age groups: 40,094 infants (LBW morbidity, LBW mortality, SIDS and respiratory syncytial virus (RSV)); 101,764 children 1-2 years of age (pneumonia and bronchitis/ bronchiolitis), 195,555 infants and children 0-3 years of age (otitis media); and 814,909 children 1-17 years of age (asthma).

The analysis showed that 29,223 infants and children had health outcomes attributable to SHS in public housing in 2011: 799 with LBW morbidity, 11 with LBW mortality, 16 with SIDS, 482

with lower respiratory infections (e.g., RSV, pneumonia and bronchitis/bronchiolitis), 13,510 with otitis media, and 14,400 with asthma.

For all of the SHS-attributable health outcomes among public housing residents in 2011, the total economic burden was calculated at ~\$138 million for diseases in adults and ~\$183 million for diseases in children. Asthma and IHD accounted for 99.9% of SHS-related morbidity and mortality in adults. Childhood asthma and premature death of infants due to LBW accounted for ~\$101 million in societal costs.

Overall, the public health and economic burden associated with SHS exposure in public housing was found to be significant. The total economic burden due to SHS exposure in “never smoker” adults and children residing in public housing in 2011 was calculated at ~\$322 million. Children had higher total direct medical costs and higher productivity losses compared to adults.

The average cost per adult or child affected by SHS exposure was calculated at \$6,062. A total of 207 adults and children residing in public housing lost their lives due to SHS exposure in their homes. A smoke-free policy in public housing potentially could improve the health of residents and reduce societal costs.

Dr. Kapil moderated ACCLPP’s discussion with Dr. Mason on CDC’s study to determine the public health and economic burden of SHS exposure in public housing. The discussion topics included:

- voluntary implementation of smoke-free policies by ~300 public housing authorities across the country and their success rate in actually enforcing these bans;
- the potential for the findings of CDC’s study to be skewed based on overlapping causes of death (e.g., asthma and lung cancer) listed on death certificates;
- the need for future research to determine the number of deaths from radon exposure in never smokers residing in public housing;
- the need for better mechanisms to link public housing residents to smoking cessation programs offered by state and local health departments; and
- HUD’s extension of the November 5, 2012 deadline to submit public comments on its proposed public housing policy.

ACCLPP encouraged CDC to leverage additional funding from HUD to support two activities. First, CDC could host webinars to present the findings of its SHS exposure study to local public housing authorities across the country. Second, CDC could compile, analyze and publish HUD data to demonstrate the public health benefits of ~300 public housing authorities across the country that have voluntarily implemented smoke-free policies.

Update by the Laboratory Workgroup (LWG)

Patrick Parsons, PhD

Chief, Laboratory of Inorganic and Nuclear Chemistry
New York State Department of Health
ACCLPP Member & Laboratory Workgroup Chair

Dr. Parsons covered the following topics in his update to ACCLPP on LWG's recent activities. The LWG members represent ACCLPP, CDC, the California CLPPP, Association of Public Health Laboratories (APHL), Quest Diagnostics, and Wisconsin State Laboratory of Hygiene.

For part 2 of its charge, ACCLPP advised LWG to address the need for recommended standards of practice for users of point-of-care (POC) blood lead testing devices. LWG held 8 web conferences from February 2011-October 2012. During the most recent web conferences, LWG finalized questions for Magellan Biosciences, clarified outstanding issues on the draft recommendations with Magellan Biosciences, and revised the practice standards for POC devices. The LeadCare POC device was developed by Magellan Biosciences to assess lead exposure in the field, but users need industry standards to ensure the quality of measurements.

Dr. Parsons highlighted LWG's revisions to its draft recommendations following ACCLPP's formal adoption of the reference value BLL ≥ 5 $\mu\text{g/dL}$ (RVBLL) during the November 2011 meeting. (*Editor's note:* The changes are highlighted in bold.)

Recommendation 12 focuses on "repeat testing of the original specimen." The recommendation states that if the initial result is ≥ 5 $\mu\text{g/dL}$, the original specimen should be reanalyzed if volume permits. The guidance clarifies "acceptable" differences in repeat testing for users of the LeadCare device: a discrepancy of >3 $\mu\text{g/dL}$ for the concentration range of **5-20 $\mu\text{g/dL}$** ; a discrepancy of >4 $\mu\text{g/dL}$ for the concentration range of 21-40 $\mu\text{g/dL}$; and a discrepancy in 10% of samples for the concentration range of >40 $\mu\text{g/dL}$.

Further investigation would be warranted for discrepancies outside of these acceptable differences. If discrepancies are identified, obvious outliers should be discarded and the average of the 2 remaining values should be reported. The patient should be referred for confirmatory testing for any result exceeding **5 $\mu\text{g/dL}$** or if the validity of the test is uncertain.

Recommendation 13 focuses on "confirmatory testing." The recommendation states that if the BLL is ≥ 5 $\mu\text{g/dL}$, the laboratory must refer either the patient or the venous blood sample for confirmatory testing. The guidance clarifies that the BLL of **5 $\mu\text{g/dL}$** was selected to maximize identification of children with lead poisoning.

CDC commented that the revised language in recommendation 13 did not match the manufacturer's instructions for use of the LeadCare II device as approved by the Food and Drug Administration (FDA). LWG shared the revised recommendation with Magellan Biosciences

and was informed of its willingness to modify the package insert with instructions to retest specimens with BLLs ≥ 5 $\mu\text{g/dL}$.

Recommendation 16 is “reporting BLLs 5-10 $\mu\text{g/dL}$ on patient reports.” Reference ranges must indicate that BLLs 5-9 $\mu\text{g/dL}$ have been associated with adverse health effects in children ≤ 6 years of age. The guidance attempts to resolve an ongoing conflict and clarifies that laboratory reports should not indicate BLLs < 10 $\mu\text{g/dL}$ are “normal.” **The recommendation was deleted.** Based on ACCLPP’s formal adoption of the RVBLL ≥ 5 $\mu\text{g/dL}$, LWG found the language to be redundant.

Recommendation 17 is “method comparison” to ensure that POC BLLs are periodically compared with confirmatory testing. The guidance clarifies “acceptable” differences between screening and confirmatory results: a discrepancy of > 3 $\mu\text{g/dL}$ for the concentration range of **5-20 $\mu\text{g/dL}$** ; a discrepancy of > 4 $\mu\text{g/dL}$ for the concentration range of 21-40 $\mu\text{g/dL}$; and a discrepancy in 10% of samples for the concentration range of > 40 $\mu\text{g/dL}$.

In addition to revising the POC recommendations, LWG also discussed the potential implications of reference laboratories shifting to the RVBLL ≥ 5 $\mu\text{g/dL}$. Current laboratory practice is to repeat blood lead analysis on a fresh aliquot of the original specimen for all results initially found to be ≥ 10 $\mu\text{g/dL}$. The analysis is repeated when the initial result is elevated to avoid false-positive results due to possible laboratory contamination errors and also to add confidence to the reported value.

CDC provided comments on LWG’s proposal to change the repeat threshold to BLLs ≥ 5 $\mu\text{g/dL}$. The CDC laboratory is evaluating the proposed change for its own blood lead analyses. Of 5,849 blood lead results that CDC reported in 2011, 3.8% were ≥ 10 $\mu\text{g/dL}$. CDC noted that if the repeat threshold was lowered to BLLs ≥ 5 $\mu\text{g/dL}$, the number of repeat tests would be doubled to 7.7%.

Despite the increase in the laboratory workload, however, CDC agreed that the revised repeat threshold of BLLs ≥ 5 $\mu\text{g/dL}$ would be manageable and desirable to improve the quality of test results. Partners in the commercial laboratory sector also confirmed their compliance if the repeat threshold of BLLs ≥ 5 $\mu\text{g/dL}$ is established as the new industry standard.

Based on agreement by CDC and commercial laboratories on the need to shift to a repeat threshold of BLLs ≥ 5 $\mu\text{g/dL}$, LWG drafted three new recommendations that are outside of its original charge.

New Recommendation 19: All blood lead tests performed in high-complexity laboratories that initially are found to be elevated (*i.e.*, ≥ 5 $\mu\text{g/dL}$) should be retested and confirmed using a fresh aliquot from the original specimen. Any observed discrepancies that are greater than the consensus limits should be resolved with additional retesting as necessary if the volume of remaining blood permits.

New Recommendation 20: All blood lead test reports on young children issued by high complexity laboratories should include the reference range of ≥ 5 $\mu\text{g/dL}$ as recommended by ACCLPP.

New Recommendation 21: Routine blood lead results should be rounded to the nearest integer for routine clinical purposes. Test results calculated as “X.5 $\mu\text{g/dL}$ ” should be rounded up if “X” is odd (e.g., 5.5 would become 6 $\mu\text{g/dL}$) and rounded down if “X” is even (e.g., 4.5 would become 4 $\mu\text{g/dL}$).

Dr. Parsons highlighted issues that need to be resolved for the three new recommendations. For recommendation 20, the range of BLLs for adults is not addressed. Some laboratory reports indicate BLLs for adults of <25 $\mu\text{g/dL}$ or <40 $\mu\text{g/dL}$. NHANES data will influence an increase or decrease in the value in the future. LWG concluded that 2007-2010 NHANES data should not be added to blood lead test reports. LWG was unable to reach agreement on whether blood lead test reports should include additional interpretations based on the BLL range, highly elevated BLLs, or a medical emergency with BLLs ≥ 70 $\mu\text{g/dL}$.

For recommendation 21, some laboratories report blood lead test results for clinical purposes to 0.1 $\mu\text{g/dL}$ (e.g., 5.6 $\mu\text{g/dL}$) or 12.2 $\mu\text{g/dL}$. This practice implies a level of analytic imprecision that is not supported by routine clinical methods. For example, some laboratories may improperly interpret consecutive results of 5.1 $\mu\text{g/dL}$ and 5.8 $\mu\text{g/dL}$ as an indication of an increased trend in blood lead concentration.

For recommendation 21, most software programs used by laboratories do not have the capacity to round blood lead values up or down. As a result, information technology systems would need to be modified at an additional cost for laboratories to comply with this guidance. Overall, the three new recommendations would either update or maintain CDC’s 1997 Laboratory Guidance Document (www.cdc.gov/nceh/lead/publications/1997/pdf/c1.pdf).

During its upcoming web conferences in 2013, LWG will place more emphasis on addressing the remaining parts of its charge. For “alternate matrices to assess lead exposure,” ACCLPP charged LWG with investigating and reporting its findings on the efficacy, reliability and validity of measuring lead in saliva as an index of lead exposure. To a lesser extent, ACCLPP also charged LWG with investigating and reporting its findings on the reliability and validity of measuring lead in other non-traditional matrices (e.g., sweat, hair, nails and packed red cells) as indices of lead exposure.

For “environmental lead analytical issues,” ACCLPP charged LWG with investigating and reporting its findings on the reliability of current technologies for assessing the lead content of paint, plastics and other environmental samples as well as laboratory capacity for handling these samples. LWG’s literature review and analysis will include the use of handheld X-ray fluorescence (XRF) analyzers in assessing lead in consumer products and the use of area concentrations versus mass fractions in assessing risks for lead exposure.

For “reference intervals for adult lead exposure,” ACCLPP charged LWG with investigating and reporting its findings on strategies for clinical laboratories to report the reference interval for adult lead exposure. LWG is aware that many laboratories currently report <30 µg/dL or <20 µg/dL as “normal” for adult BLLs.

ACCLPP made the following comments and suggestions for LWG to consider in its ongoing efforts to fulfill its charge.

- ACCLPP should engage professional societies, particularly APhL, to send a letter to clinical laboratories to emphasize the critical need to adopt the RVBLL ≥ 5 µg/dL as the industry standard and modify their practices accordingly. Mandatory standards or regulations do not currently exist that require clinical laboratories to change their practices for the RVBLL ≥ 5 µg/dL. The target audience of the letter should include clinical laboratories that participate in proficiency testing programs and are registered with the Centers for Medicare and Medicaid Services (CMS) for blood lead testing.
- LWG should change the language in recommendation 13 to: “The BLL of 5 µg/dL was selected to maximize identification of children with elevated blood lead levels.”
- LWG should obtain technical expertise from CDC in calculating the 97.5th percentile to determine whether the same RVBLL ≥ 5 µg/dL for children could be applied to protect the health of adults, particularly pregnant women and women of childbearing age. A uniform reference value for both children and adults would minimize confusion and facilitate easier implementation by laboratories. Drs. Michael Kosnett, Walter Rogan and Megan Sandel offered to assist Dr. Parsons in drafting language on a uniform reference value. The draft recommendation would be presented during the business session on November 16, 2012 for ACCLPP’s review, discussion, revision and formal adoption.

Dr. Brown noted that due to time constraints, LWG would be extremely challenged in calculating a uniform RVBLL for adults and presenting the draft recommendation for ACCLPP’s formal vote on the last day of the meeting. As a more feasible option, she and Mr. Jarrett would work with LWG after the meeting to update CDC’s 1997 Laboratory Guidance Document. The revised document would be distributed to ACCLPP for review and comment and a teleconference would be convened for ACCLPP’s formal vote.

With this approach, Dr. Brown pointed out that the ACCLPP members would have much more time to review and submit comments on a written document. However, she explained that ACCLPP would still have the option of issuing interim guidance in a shorter time frame if the update to CDC’s 1997 Laboratory Guidance Document takes more time than expected.

Update by the Educational Intervention Workgroup (EIWG)

Sher Lynn Gardner, MD

Assistant Professor of Pediatrics, Department of Pediatrics, Emory University
ACCLPP Member & Educational Intervention Workgroup Chair

Dr. Gardner explained that the EIWG members represent ACCLPP, CDC, academic institutions, CDC-funded CLPPPs, U.S. Department of Education, professional societies, community-based organizations, parents and advocates of children with EBLLs, and other external experts (e.g., pediatricians, psychologists and early childhood educators). She devoted her update to ACCLPP's review and discussion of EIWG's draft report that was distributed in advance of the meeting.

The overarching purpose of the report is to provide guidance and serve as a comprehensive resource on advocating and intervening on behalf of children with known EBLLs or deficits believed to be associated with EBLLs. The report also highlights current regulations to support the recommendations. The target audiences of the report include public health practitioners, educational professionals, teachers, healthcare providers, and parents/caregivers

Dr. Gardner provided descriptions on specific sections of the draft report to guide ACCLPP's discussion. The "Executive Summary" summarizes ACCLPP's charge to EIWG. Chapter 1 ("Introduction") describes the prevention of exposures to lead as the only effective strategy to eliminate educational deficits in children. The Introduction also covers the benefits of early intervention, the need for collaborative efforts among all caregivers of children with EBLLs, federal regulations that currently support children with EBLLs, and clinical trials on the effects of lead on IQ.

Chapter 2 ("Neurodevelopmental Consequences of Lead Exposure") compiles a compelling body of scientific evidence on this issue. However, EIWG needs ACCLPP to submit citations of other well-designed studies. The additional data will help EIWG to better describe the relationship between early childhood lead exposure and decreased IQ/increased behavioral problems in terms of attention, executive function, visual-spatial skills, social behavior, speech and language, and fine and gross motor skills.

Chapter 4 ("Consequences of Lead on Learning and Educational Attainment") is incomplete at this time, but data gaps to drive the development of a research agenda will be highlighted. Most notably, the lack of prospective studies on the effectiveness of early childhood education and other non-medical interventions in ameliorating the effects of EBLLs in children will be emphasized.

Chapter 5 ("Effectiveness of Early Childhood Education Programs") cites multiple studies to demonstrate the effectiveness of early childhood education (ECE) programs. Detailed descriptions are provided on the overall quality of the Head Start Program, outcomes of children

with disabilities who have participated in ECE programs, and the costs and benefits of ECE programs.

Chapter 6 (“Educational Resources for Improving the Academic Performance of Children Affected by Lead”) is incomplete at this time. EIWG will compile a list of resources for parents, medical providers and schools to complete this chapter.

Chapter 7 (“Individual Regulations Unveiled”) provides details on sections of the Individuals with Disabilities Education Act (IDEA) that are relevant to children with EBLLs. Chapter 8 (“What are the Roles of Childhood Lead Poisoning Prevention Programs and School Departments?”) is incomplete at this time. New sections on the roles of healthcare providers and other stakeholders who serve as caregivers to children will be added to this chapter. The roles of these various groups will be compiled in a chart or decision tree.

Dr. Gardner solicited input from ACCLPP on the draft report. However, she asked ACCLPP to refrain from extensive wordsmithing because the current version is an extremely rough draft that has not yet undergone a thorough editorial, grammatical or typographical review. To assist EIWG in drafting the next iteration, she asked ACCLPP to provide feedback on global issues (e.g., significant errors or misinterpretation of the data).

ACCLPP’s comments and suggestions on the draft educational intervention report are outlined below.

General Comments

- The report aims to provide guidance on specific educational interventions to improve the health, cognition or neurodevelopmental abilities of children with EBLLs, but this goal is not achieved due to research gaps in this area. As a result, EIWG should consider the possibility of separating the draft report into two distinct documents.
 - The “Educational Resource” document should succinctly describe educational resources (e.g., IDEA, Special Education Programs and model regulations) that are available to children with EBLLs in a fact sheet of no more than 4 pages.
 - The more detailed and comprehensive “Educational Intervention” document should reference the literature to drive the development of a strong educational intervention research agenda for children with EBLLs, serve as an educational tool for clinicians, and facilitate the creation of a uniform vocabulary across target audiences.
- EIWG should develop a new chapter to describe the role of practicing pediatricians in interacting with the educational system. Alternatively, this issue should be prominently featured in the Executive Summary.
- EIWG should engage additional educational expertise to further vet the draft report. The expertise of the ACCLPP members primarily focuses on health and toxicological effects of lead. To address this suggestion, Dr. Brown confirmed that she would consult with federal partners at the Health Resources and Services Administration who have expertise in early interventions for children.

- EIWG should include strong guidance throughout the report on removing the child from the lead source. This guidance should be used to inform the target audiences of the need to request home visits and home assessments in addition to implementing educational interventions.

Executive Summary

- Reconcile the terminology (e.g., “children with unusually high blood lead levels,” “lead-poisoned children,” “children with elevated blood lead levels,” and “children affected by lead”) to ensure consistency and clarity throughout the report.
- Clarify the second recommended intervention to improve child outcomes (e.g., “an inventory and consistent interpretation of existing regulatory and policies...”).
- Add language to describe the context in which children with a history of EBLs are “entitled” to receive services.
- Revise the language on developing a research agenda regarding the effectiveness of educational interventions: “particularly for children with low level (*i.e.*, blood lead levels <45 mcg/dL) lead exposure.”

Chapter 1: Introduction

- Delete the following sentence and its three references because studies have not been conducted or rigorous behavioral interventions have not been implemented to date to support this language: “Once a child’s health or cognition has been harmed by lead, the effects are permanent and continue into adulthood.” Replace the sentence with the following language: “Data exist that suggest lead exposure in early childhood causes long-lasting effects.” Ms. Ruth Ann Norton is the ACCLPP liaison representative for the Coalition to End Childhood Lead Poisoning. She offered to provide EIWG with supporting data to maintain the existing language (e.g., studies showing no improvement after children with EBLs received significant educational interventions and studies demonstrating the permanent loss of intelligence scores among children with EBLs).

Chapter 2: Neurodevelopmental Consequences of Lead Exposure

- Change the 2012 National Toxicology Program reference from “attention deficit disorder” to “attention-related behavior.”
- Include the updated Lanphear, *et al.* pooled analysis that was conducted for the European Food Safety Association. Ms. Reva Berman is a Policy and Program Advisor for Health Canada. She would e-mail the citation to Dr. Brown for distribution to EIWG.
- Differentiate between impacts of lead exposure on attention and clinical diagnosis of attention deficit hyperactivity disorder (ADHD).
- Delete the term “neurobehavioral signature” and describe the impact of lead on multiple domains.

Chapter 5: Effectiveness of Early Childhood Education Programs

- Delete the text and citations for the two animal studies: the 2001 Schnieder study and the 2003 Guilarte study. Cite human studies only to demonstrate the effectiveness of ECE programs.

- Relocate the section describing outcomes of children with disabilities who have participated in ECE programs to the beginning of the chapter to immediately explain the rationale for educational interventions to children with EBLs.

Dr. Cory-Slechta closed the discussion with agreement for the ACCLPP members to submit additional comments and references to Drs. Brown and Gardner to assist EIWG on drafting the next iteration of the report.

Public Comment Session

Jacqueline Mosby, MPH

Chief, Program Assessment and Outreach Branch
U.S. Environmental Protection Agency

Ms. Mosby announced that EPA recently has taken 16 enforcement actions for the Lead Renovation, Repair and Painting Rule.

With no further discussion or business brought before ACCLPP, Dr. Kapil recessed the meeting at 4:08 p.m. on November 14, 2012.

Opening Session: November 15, 2012

Vikas (“Vik”) Kapil, DO, MPH, FACPOEM

Chief Medical Officer and Associate Director for Science, NCEH/ATSDR
Centers for Disease Control and Prevention
Acting ACCLPP Chair and Designated Federal Official

Dr. Kapil opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. He confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 15, 2012. He reconvened the proceedings at 8:48 a.m. and welcomed the participants to day 2 of the meeting.

Dr. Kapil reminded the ACCLPP voting members of their individual responsibility to identify real or perceived conflicts of interest with any of the published agenda items and recuse themselves from participating in these matters. None of the ACCLPP voting members disclosed any conflicts of interest for the record for day 2 of the meeting.

John Kastenbauer

Chief, Federal Advisory Committee Management Branch/MASO
Centers for Disease Control and Prevention

Mr. Kastenbauer joined the meeting to answer questions or clarify any outstanding issues related to ACCLPP's charter. This new item was placed on the agenda to assist ACCLPP in drafting the letter to the HHS Secretary and CDC Director in accordance with its charter.

Mr. Kastenbauer explained that ACCLPP's letter should focus on the scientific aspects and public health practice of national childhood LPP efforts and include concrete recommendations on new programs to benefit these efforts at state and local levels. ACCLPP also is free to provide guidance on existing programs that are no longer viable. However, neither ACCLPP nor any other Federal Advisory Committee (FAC) is chartered to advise the HHS Secretary and CDC Director on funding allocations to programs or make specific recommendations on the budget.

ACCLPP emphasized that its overarching goal is for the HHS Secretary and CDC Director to seriously consider and take action on the letter. As a result, ACCLPP was aware of the need to draft the letter within the scope of its charter. Several members made comments in follow-up to Mr. Kastenbauer's remarks.

Dr. Sandel acknowledged the difficulty in not alluding to budgetary aspects in the letter because current prevention practices are inadequate based on science. Most notably, the letter will discuss CDC's approval of ACCLPP's recent recommendations that will identify thousands of additional children at risk for adverse outcomes from low-level lead exposures.

ACCLPP also is interested in conveying that based on the science in changing the level of concern (LOC) BLL ≥ 10 $\mu\text{g/dL}$ to the RVBLL ≥ 5 $\mu\text{g/dL}$, the current LPP budget is grossly inadequate to protect this new population of children. Moreover, the *Healthy People 2020* objective of reducing disparities in childhood lead poisoning will not be met with the loss of the LPP budget.

Mr. Gottesfeld was confused by some of Mr. Kastenbauer's remarks because the charter contains no language that prohibits ACCLPP from commenting on CDC's budget for LPP activities. He questioned CDC's attempt at censorship before ACCLPP drafted the letter.

Ms. Malone noted that the language in the charter to "recommend improvements in national childhood lead poisoning prevention efforts" appears to allow ACCLPP to provide guidance on LPP activities beyond CDC/HHLPPP and across HHS.

Mr. Kastenbauer made several remarks in response to ACCLPP's specific questions and comments.

- ACCLPP's letter could recommend that "X" number of states continue to provide LPP services to protect the health of children. The letter also could include a discussion on the cost-effectiveness, return on investment and public health benefits of LPP science.
- Advice and recommendations by the FAC should be consistent with the objectives, scope of activities and description of duties outlined in its charter. None of these

sections mention work or advice by the FAC concerning budgetary matters. The focus of the FAC always should be directed to programmatic and scientific matters pertinent to the subject matter of the FAC.

- Letters, consensus recommendations, position statements or other documents drafted by the FAC are sent to MASO for review before being forwarded to the CDC Director and/or HHS Secretary. For documents that MASO determines to be outside of the FAC's charter, MASO contacts the DFO of the FAC to discuss options to proceed. For example, the FAC Chair could be asked to revise the document to be consistent with the charter.

PANEL PRESENTATION: FEDERAL AGENCY RESPONSES TO THE ACCLPP RECOMMENDATIONS

CDC, ATSDR and the ACCLPP *ex-officio* members presented responses by their federal agencies to ACCLPP's recommendations on low-level lead exposures, including preliminary implementation plans, proposed strategies and major challenges. The presentations are set forth below.

Agency Response: Centers for Disease Control and Prevention

Mary Jean Brown, ScD, RN

Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Brown presented CDC's response to the ACCLPP recommendations. In late 2010, ACCLPP formed a workgroup to address CDC's charge to evaluate new approaches, terminology, and strategies for defining EBLLs among children. In January 2012, ACCLPP voted to formally adopt 13 recommendations proposed by the workgroup that were designed to focus the nation's efforts on primary prevention as the most essential strategy to eliminate childhood lead poisoning through targeted interventions for individual children and communities with BLLs at or above the reference value for lead of 5 µg/dL.

In May 2012, CDC responded to the ACCLPP recommendations based on one of three options. To concur, CDC would agree to implement the recommendation based on available funding, staff and control. To concur in principle, CDC would agree that the recommendation should be implemented, but funding, staff or control was not available. When feasible, however, CDC would request funding or other necessary resources and implement the recommendation if the request was approved. To not concur, CDC would disagree with the recommendation and provide its rationale for disagreement. CDC either "concurred" or "concurred in principle" with all 13 of ACCLPP's recommendations.

After meeting with key staff at EPA and HUD in August 2012, CDC and its federal partners presented the ACCLPP recommendations and a status report on implementation, challenges and future directions to the Presidential Task on Children's Environmental Health in September 2012. Of the 13 ACCLPP recommendations, 4 fall within CDC's direct control.

Recommendation 1: Based on the scientific evidence, ACCLPP recommends that (a) the term "level of concern" be eliminated from all future agency policies, guidance documents and other CDC publications, and (b) current recommendations based on the "level of concern" be updated according to the recommendations contained in the report.

CDC concurred with recommendation 1 and outlined its specific means to address or implement this guidance. CDC/HHLPPB has discontinued its use of the term "LOC." All current and future CDC publications will replace LOC with the reference value and the date NHANES used to calculate the reference value.

CDC will issue the following standard language for clinical settings: "A level at or above the reference value for blood lead that is established as the 97.5th percentile for the distribution of BLLs of U.S. children 1-5 years of age (5 µg/dL in 2012) is unusual/atypical. BLLs at or above the reference value indicate a child is exposed to lead above that experienced by most children in the same age group. Further assessment of the child and his/her environment is warranted."

CDC will issue the following standard language for publications: "The reference value for U.S. children 1-5 years of age is the 97.5th percentile of the population blood lead distribution (5 µg/dL in 2012)." CDC will issue the following standard language for a population or community: "On a community basis, any distribution of BLLs significantly higher than that of the U.S. childhood population 1-5 years of age indicates the community has lead sources in the environment that put children living there at higher risk for unusual/atypical BLLs than the general U.S. childhood population."

HHLPPB will make the standard language available to operating divisions across CDC and also will use the formal cross-clearance and review process to ensure that authors in other National Centers adopt this language prior to the release of documents. Materials on the website (www.cdc.gov/nceh/lead) will use terminology that existed at the time of their publication.

The 1975-1991 CDC Lead Statement contains the following footnote: "These documents are being kept on this website for historical purposes and are no longer in print." The footnote also will be added to the 2005 CDC Lead Statement along with additional language: "These documents refer to various blood lead thresholds and levels of concern for adverse health outcomes in children. This terminology is no longer current and readers should refer to the 2012 ACCLPP recommendations that are available at: http://www.cdc.gov/nceh/lead/ACCLPP/CDC_Response_Lead_Exposure_Recs.pdf."

A similar statement was applied to the CDC 2002 paper, *Managing Elevated Blood Lead Levels Among Children*: "This document refers to a blood lead level of 10 µg/dL as the CDC level of concern for adverse health outcomes in children. This terminology is no longer current and

readers should refer to the ACCLPP 2012 recommendations. However, the 2012 document does not recommend changes to guidelines for the evaluation and treatment of children requiring chelation (those with BLLs ≥ 45 $\mu\text{g}/\text{dL}$) published here.”

CDC’s response to recommendation 1 included a comment that the statement would be placed on www.cdc.gov/nceh/lead no later than March 1, 2012. A joint publication summarizing the ACCLPP recommendations and CDC’s response would be submitted to the *MMWR* and *Pediatrics* no later than May 2012. Although the statement was placed in the *MMWR* on May 25, 2012, NCEH subsequently decided that a joint publication would not necessary because the documents are available on the website.

CDC participated in a webinar for EPA and ATSDR regional staff, Pediatric Environmental Health Specialty Units, and other groups in Region 7 to discuss the ACCLPP recommendations, CDC’s response and implications for implementation. The August 2012 webinar was held for state and local health departments and CLPPPs, while a second webinar will be convened later in the year for a diverse group of national stakeholders

Based on these actions, CDC’s position is that recommendation 1 is being addressed. Statements will be applied to historical documents by the end of 2012. A section of the CDC website (www.cdc.gov/nceh/lead) will be dedicated to the 2012 ACCLPP recommendations and CDC’s response to allow for easier retrieval and reference.

Recommendation 8: CDC should encourage local, state and other federal agencies to: (a) facilitate data-sharing between health and housing agencies; (b) develop and enforce preventive lead-safe housing standards for rental and owner-occupied housing; (c) identify financing for lead hazard remediation; and (d) provide families with information needed to protect their children from lead hazards in the home.

CDC concurred with part (d) of recommendation 8 and outlined its specific means to address or implement this guidance. CDC utilized a wide variety of networks and media outlets to develop and distribute materials to help families identify and control or eliminate lead hazards in their homes. Many of these materials are available at www.cdc.gov/nceh/lead in both English and Spanish.

CDC recognized that the development of new materials was beyond its current capacity due to severe resource constraints, but a multi-agency website (www.healthyhomes.hud.gov) currently is under construction with representation by CDC, HUD, EPA and the U.S. Department of Agriculture. The website will include several pages related to making homes lead-safe and also will provide new information on lead-safe renovations. The federal partners expect to launch the new website early in 2013. Based on these actions, CDC’s position is that part (d) of recommendation 8 is being addressed.

Recommendation 10: CDC should (a) emphasize the importance of environmental assessments to identify and mitigate lead hazards before children demonstrate BLLs

above the reference value and (b) adopt prevention strategies to reduce environmental exposures from lead in soil, dust, paint and water before children are exposed.

CDC concurred with part (a) of recommendation 10 and outlined its specific means to address or implement this guidance. For over 20 years CDC, has and will continue to emphasize the importance of environmental assessments and mitigation of lead hazards before children are exposed (e.g., before their BLLs are above the reference value) in CDC policies, CoAgs, interagency agreements and publications.

NCEH/ATSDR established a workgroup to consider the best strategies for implementing primary prevention at Superfund cleanup sites and determining the appropriate screening value for lead in soil. ATSDR's existing policy is that soil with lead concentrations below the screening value is considered to be of minimal risk.

ATSDR may consider various approaches to address contaminated sites, such as "lead-safe" measures that control soil lead hazards. ATSDR also may consider "lead-free" measures that require complete replacement of lead-contaminated soil based on lead concentrations and the risk for exposure to vulnerable populations (e.g., children and pregnant women). Based on these actions, CDC's position is that part (a) of recommendation 10 is being addressed.

Recommendation 13: Additional research priorities should include efforts to improve the use of data from screening programs, develop next generation point-of-care lead analyzers, and improve the understanding of epigenetic mechanisms of lead action

CDC concurred with recommendation 13 and outlined its specific means to address or implement this guidance. CDC is continuing to collaborate with the National Institute of Environmental Health Sciences (NIEHS), academic partners and laboratory instrument manufacturers to encourage research in these important areas. Based on its ongoing interactions with NIEHS and other groups to foster collaboration in developing a research agenda, CDC's position is that recommendation 13 is being addressed.

CDC is aware that the shift from the LOC BLL ≥ 10 $\mu\text{g}/\text{dL}$ to the RVBLL ≥ 5 $\mu\text{g}/\text{dL}$ will have implications in several areas other than federal policy. CDC currently is supporting ACCLPP workgroups to address early childhood education and laboratory proficiency testing and also will make efforts in the future to focus on nutrition.

Agency Response: Agency for Toxic Substances and Disease Registry

William Cibulas, PhD

Senior Advisor for Public Health

NCEH/ATSDR Office of the Director

Dr. Cibulas presented ATSDR's response to the ACCLPP recommendations. ATSDR fully supports and endorses the ACCLPP recommendations and is currently devising strategies to

conduct specific activities that affect ATSDR's site-specific work in communities. However, ATSDR has no plans at this time to update the lead ToxProfile™. The document was last revised in 2007.

Several factors drive ATSDR's lead activities at sites. The Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) mandates ATSDR to conduct public health assessments (PHAs) at sites on the EPA National Priorities List (NPL), determine whether a threat to public health exists at the site, and take various public health actions to mitigate the threat.

CERCLA also mandates ATSDR to maintain the Priority List of Hazardous Substances by ranking the most hazardous substances found at waste sites on a biennial basis. Lead is the number 2 hazardous substance on the list and is the most frequently found contaminant of concern at waste sites across the country. Lead has been detected in completed exposure pathways at hundreds of sites and is a chemical of concern. Residential soil where children live and play continues to be the most important pathway of concern in ATSDR's activities in communities.

ATSDR used EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) model to derive a screening value for lead. ATSDR performed modeling and established 400 ppm of lead in residential soil as the "unofficial" screening value based on BLLs ≥ 10 $\mu\text{g/dL}$. EPA uses ATSDR's screening value as a preliminary remediation goal and a cleanup standard at sites as well. ATSDR also performs a rigorous review of BLL data when available for environmental screening.

ATSDR is closely collaborating with EPA to implement the ACCLPP recommendations. The federal partners performed calculations to determine changes in using the IEUBK model as a screening approach at sites to analyze lead levels in the environment when the RVBLL ≥ 5 $\mu\text{g/dL}$ was applied.

The calculations dramatically lowered the screening value for lead in residential soil to a range of ~80-150 ppm depending on the data and default assumptions input into the model. ATSDR and EPA acknowledged that the change would have serious implications for their activities in communities because residential soil lead levels of 80-150 ppm are found at many more sites.

ATSDR and EPA held a meeting in September 2012 to explore strategies that would place more emphasis on risk factors and vulnerabilities in communities earlier in the PHA process. Based on the outcomes of this meeting, the federal partners currently are piloting a risk factor screening tool for lead at the ACM Smelter and Refinery site in Black Eagle, Montana. ATSDR welcomes the opportunity to present preliminary findings from the risk factor screening tool for lead during the next ACCLPP meeting.

The tool is designed to analyze both environmental data and various risk factors that increase a community's vulnerability to lead (e.g., demographics, BLLs in children, potential lead sources and age of housing). ATSDR and EPA also are revising health messages to healthcare

providers, communities and other stakeholders to clearly communicate changes that will occur as a result of the RVBLL ≥ 5 $\mu\text{g/dL}$.

ATSDR currently is making efforts to complete PHAs at sites in three categories: (1) sites with lead in soil ≥ 400 ppm, (2) sites with $>5\%$ of BLLs ≥ 10 $\mu\text{g/dL}$, and (3) sites with lead in soil ≤ 100 ppm and BLLs < 5 $\mu\text{g/dL}$. Although the sites in category 3 are the most difficult to address, only 10 sites fall in this group. ATSDR will continue to conduct PHAs at sites with lead in soil 100-400 ppm and BLLs 5-10 $\mu\text{g/dL}$. ATSDR also is considering collaborative efforts with state and local public health agencies to increase its role in primary prevention in communities.

ATSDR has educated its public health assessors on the ACCLPP recommendations and the new interagency strategy for ATSDR and EPA to more carefully and critically consider risk factors in communities. Public health assessors are conveying this information to managers in the field and communities.

Dr. Kapil moderated ACCLPP's discussion with Dr. Cibulas on the ATSDR response to the ACCLPP recommendations. The discussion topics included:

- ATSDR's potential approach of treating lead as a non-threshold acting carcinogen at sites and considering any exposure to lead as "unacceptable;"
- strategies by ATSDR and EPA to assure rigorous validation of the IEUBK model for low-level lead exposures;
- the process for private citizens, community groups and other stakeholders in the public to petition ATSDR to review environmental data, provide expert opinion on whether a hazard is present at the site, and conduct a PHA if necessary; and
- ATSDR's plans to conduct new PHAs at sites with lead in soil ≤ 100 ppm and BLLs < 5 $\mu\text{g/dL}$.

ACCLPP made comments and suggestions in two areas for ATSDR to consider in formulating an implementation plan for the recommendations.

- ATSDR should partner with EPA to improve its efforts to address multi-metal exposures at sites. Chemical mixtures continue to be a tremendous EH concern in communities. The IEUBK model is lead-specific, but EPA has issued guidance on cumulative risk assessments since 1994.
- ATSDR should reconsider its decision not to update the lead ToxProfileTM at this time. Although the document was last revised in 2007, compelling data have been produced over the past 5 years that would strengthen the science of the lead ToxProfileTM.

In addition to the discussion with Dr. Cibulas on the ATSDR response, ACCLPP also engaged in extensive dialogue with Dr. Brown on the CDC response. In light of CDC's concurrence with the recommendation to eliminate the term LOC from all future policies, guidance documents and other publications, ACCLPP emphasized the need for standardized language to convey the RVBLL ≥ 5 $\mu\text{g/dL}$.

In its response to recommendation 1, for example, ACCLPP advised CDC to replace the proposed term “unusual (atypical)” with “BLLs that are higher than those in the top 2.5% of the population.” Several ACCLPP members found CDC’s proposed language to be vague and confusing for clinicians and communities.

In terms of laboratory settings, ACCLPP pointed out that pediatricians receive blood lead results from laboratory test reports rather than from CDC. Standardized laboratory language should be developed because multiple terms are used in laboratory test reports to characterize BLLs above the reference value, including “abnormal,” “elevated,” “high” or “medical emergency” (e.g., BLLs ≥ 70 $\mu\text{g/dL}$).

For outreach efforts to clinical, laboratory and community settings, ACCLPP was in favor of sending letters to the American College of Medical Toxicology, American Association of Pediatrics, APHL and other professional societies to encourage their respective memberships to adopt standardized language and clearly distinguish between the RVBLL ≥ 5 $\mu\text{g/dL}$ and BLLs that truly require medical interventions. Several members pointed out that use of the term “lead poisoned” versus “elevated” would prompt more parents and clinicians to take action. Overall, ACCLPP agreed that standardized language must be developed for the general public to understand, embrace and promote primary prevention.

Dr. Brown closed the discussion by describing CDC’s next steps in its implementation plan for the ACCLPP recommendations. For laboratory settings, she and Mr. Jarrett would reformat the slide set Dr. Parsons presented on the previous day into a narrative that would be circulated to LWG over the next few weeks. LWG would use the narrative to draft recommendations on standardized language for laboratories to report the RVBLL ≥ 5 $\mu\text{g/dL}$ and calculate a uniform reference value for adults. Dr. Kosnett volunteered to assist LWG in this effort.

Prior to the November 2013 meeting, CDC would convene a teleconference for ACCLPP to discuss and formally vote on LWG’s new draft recommendations and the existing POC guidance. After ACCLPP’s recommendations on standardized laboratory language and a uniform reference value for adults were issued as interim guidance in the short term, LWG and CDC would focus on the longer-term effort of updating the 1997 Laboratory Guidance Document.

For clinical and community settings, Dr. Brown agreed with ACCLPP on the critical need for standardized language to clearly distinguish between the RVBLL ≥ 5 $\mu\text{g/dL}$ and “acutely lead-poisoned” children with encephalopathy, seizures or other adverse health outcomes requiring chelation. CDC is collaborating with Health Canada on the development of a color-coded graph to illustrate the distribution of blood lead at various levels. Pediatricians will be able to use the graph to pinpoint BLLs of their patients and discuss action steps with parents.

Agency Response: U.S. Environmental Protection Agency

Barnes Johnson

Deputy Director, Office of Superfund Remediation and Technology Innovation
U.S. Environmental Protection Agency

Jacqueline Mosby, MPH

Chief, Program Assessment and Outreach Branch
U.S. Environmental Protection Agency
ACCLPP *Ex-Officio* Member

Mr. Johnson and Ms. Mosby presented EPA's response to the ACCLPP recommendations.

Office of Solid Waste and Emergency Response (OSWER). OSWER's cleanup programs include long-term, multi-year involvement at sites with significant environmental contamination problems as well as short-term involvement at sites with emergencies, imminent problems or high-risk issues that require EPA's removal authority. Lead is a common issue of concern in the redevelopment of Brownfields in urban areas and cleanup of Hazardous Waste Management Program sites and federal facilities.

OSWER's major activities include evaluating sites, gathering data, conducting human health and ecological risk analyses, performing environmental investigations, designing and constructing remedies and solutions to environmental contamination, monitoring sites long-term, and considering reuse and redevelopment strategies. Science and public engagement are deeply embedded in all of OSWER's activities.

Of ~1,800 sites that currently are on the NPL for long-term cleanup, lead is a contaminant of concern at >700 sites. However, OSWER also addresses exposures to chemical mixtures from lead and other heavy metals at sites. OSWER estimates that ~150 sites have residential land use with implications for childhood exposures. Many sites under OSWER's authority include community housing developments that were built over former mining facilities, smelting operations, battery handling facilities, and metal/chemical processing plants.

OSWER is challenged when evaluating and targeting remediation at contaminated sites because the distribution of lead in soil can be irregular, variable or complex. Moreover, some sites cover large geographical areas and multiple counties in some cases. This hinders OSWER's ability to pinpoint high-level lead areas. OSWER also sometimes encounters problems in gaining access to residential properties to conduct sampling and cleanup.

OSWER's waste programs generally do not cleanup background contamination either from naturally occurring or anthropogenic sources. However, even though OSWER may not be able to cleanup up all contamination, such as that attributable to background, OSWER endeavors to maintain close partnerships with public health agencies to resolve problems related to lead and other environmental contaminants in a comprehensive manner.

OSWER acknowledges that technology plays a limited role in its cleanup activities. Most lead-contaminated soil is simply excavated, removed and replaced with clean fill. OSWER is pushing the use of new technology where possible. For example, OSWER is exploring the use and long-term efficacy of bone meal and phosphate-based treatment to reduce the bioavailability of lead. OSWER also has developed better and less expensive *in vitro* methods to measure the bioavailability of lead in the soil fraction. This method promises to be useful for developing appropriate site-specific cleanup standards.

OSWER is continuing to formulate a multi-prong strategy to respond to the ACCLPP recommendations. OSWER currently is refining its strategy with more details (e.g., specific tasks and action items, timelines, and clearly defined roles and responsibilities).

OSWER will continue its strong collaboration with ATSDR and state, local and tribal health agencies to implement all parts of the strategy, including an inventory of sites, characterization of lead exposure from both site-related and non-site-related sources, optimum management options to reduce lead exposure, blood lead monitoring to inform cleanup programs, and inclusion of other authorities as appropriate.

OSWER is aware that the ACCLPP recommendations will have implications for its current cleanup activities at sites. ACCLPP's guidance focuses on low-level lead exposures, but OSWER must continue to prioritize sites and first address those sites that have, for example, thousands of parts per million of lead in soil and known exposure to children. The number and spatial area of sites where lead poses a concern may increase. However, additional exposure modeling and technical analysis must be completed first. EPA's experience has been that even when using its existing cleanup targets, after cleanup and public education programs have been implemented at its lead-contaminated sites, BLLs in children living nearby are substantially lowered and are approaching the new RVBLL recommended by ACCLPP.

The possibility of the RVBLL changing every four years is a concern to OSWER. The specific mandate in the Superfund Program that calls for a review of sites every five years is the mechanism that often is used to consider the latest toxicity and public health information. This mandate would be the expectation with the ACCLPP recommendations. OSWER will continue to place significant reliance on public health education and other institutional controls to address exposure to lower lead levels at sites.

Office of Pollution Prevention and Toxics (OPPT). OPPT's activities for low-level lead exposure have been based on BLLs ≥ 5 $\mu\text{g}/\text{dL}$ since 2011. EPA issued the following statement in this regard: "CDC's announcement of the ACCLPP recommendations is consistent with EPA's position that no safe blood lead level has been identified for children. EPA's position on the effect of lead levels is part of a broader government goal to prevent childhood lead poisoning. However, EPA's primary charge under Title IV of the Toxic Substances Control Act is to prevent lead exposures by ensuring that individuals who engage in activities with the potential to create lead dust hazards are trained and certified to use Lead Safe Work Practices (LSWP)."

EPA's Lead-Based Paint Program historically has tracked the number of children <6 years of age with BLLs ≥ 10 $\mu\text{g/dL}$, but new studies clearly show that children are adversely affected at lower lead levels. Moreover, lead-based paint (LBP) continues to be a hazard in 38 million homes. As a result, EPA currently is tracking the number of children <6 years of age with BLLs ≥ 5 $\mu\text{g/dL}$.

EPA also established performance measures to track its progress toward eliminating childhood lead poisoning in vulnerable populations, particularly the indicator to reduce the number of children with BLLs ≥ 5 $\mu\text{g/dL}$. The 2008 National Ambient Air Quality Criteria Rule, the Renovation, Repair and Painting (RRP) Rule and other recent data support EPA's position.

EPA received a petition with a request to lower residential lead dust hazard standards. EPA agreed to revisit this issue in October 2009 and is developing approaches to derive and measure lead dust hazards at lower levels. The Science Advisory Board reviewed and supported EPA's proposal of a target BLL < 10 $\mu\text{g/dL}$. EPA currently is reevaluating residential lead dust hazard standards and is considering several sources in its decision-making process, including the ACCLPP recommendations, guidance by the Science Advisory Board and new studies. The new data may impact EPA's current lead dust levels: 40 $\mu\text{g/ft}^2$ on floors, 250 $\mu\text{g/ft}^2$ on windowsills, and 400 ppm in soil.

EPA fully implemented the final RRP Rule in 2010 and authorized 12 states to conduct RRP Programs: Alabama, Georgia, Iowa, Kansas, North Carolina, Massachusetts, Mississippi, Oregon, Rhode Island, Utah, Washington and Wisconsin. The RRP Rule requires all contractors to follow LSWP during renovations in which LBP will be disturbed. To date, EPA and the 12 authorized states have trained, accredited or certified >600 providers, >126,000 firms and >450,000 renovators in LSWP.

EPA tremendously increased its outreach efforts on the RRP Rule to empower consumers to demand LSWP-certified contractors. Most notably, Home Time TV is a nationally acclaimed television show that has agreed to produce a 6- to 7-minute segment with advice on the RRP Rule. The segment will be aired on PBS and syndicated to >1 million persons in February 2013. EPA developed and distributed online banners to >10,000 websites of high-profile media and advertising networks with links to consumer websites.

EPA updated and circulated its existing consumer print advertisements to various magazines and specifically targeted 500,000 uncertified contractors through a mass mailing of postcards. EPA revamped its radio broadcasts to provide information on the effects of lead on children from the age of a toddler through graduation. More details on EPA's outreach efforts for the RRP Rule are available at www.epa.gov/lead.

Dr. Kapil moderated ACCLPP's discussion with Mr. Johnson and Ms. Mosby on the EPA response to the ACCLPP recommendations. The discussion topics included:

- EPA's partnerships, technical assistance and expertise to ensure effective cleanup of all federal facilities in accordance with CERCLA;

- the limited ability of phytoremediation technology to protect children from exposure in and around their homes;
- EPA's plans to revise the *Risk Assessment Guidance for Superfund* for consistency with the RVBL ≥ 5 $\mu\text{g}/\text{dL}$ and communicate this change to the entire network of EPA Superfund risk assessors;
- EPA's decision-making process for "entire removal" versus "cover-up/burial" of lead-contaminated soil (e.g., region-specific or site-specific issues and volume of soil);
- the impact of uncertainty in lead dust sampling in the field on the ability of laboratories to report accurate BLLs; and
- EPA's plans to review the lead in drinking water standard.

Agency Response: U.S. Department of Housing and Urban Development

Warren Friedman, PhD, CIH

Senior Advisor, Office of Healthy Homes and Lead Hazard Control
U.S. Department of Housing and Urban Development
ACCLPP *Ex-Officio* Member

Dr. Friedman presented HUD's response to the ACCLPP recommendations. He clarified that for the sake of brevity, the full text of the ACCLPP recommendations were paraphrased.

Recommendation 1: *CDC should no longer use the term "LOC."* HUD does not use this term in its lead rules, policy notices or program documents. However, HUD quoted CDC and used this term in preambles to the 1996 Lead Disclosure Rule (LDR) and the 1999 Lead Safe Housing Rule (LSHR). HUD will not change the language in these preambles because LDR and LSHR are rulemaking documents.

Recommendation 2: *CDC should use a reference value based on the 97.5th percentile childhood BLL and update the reference value every 4 years.* HUD uses an environmental intervention BLL (EIBLL) in LSHR in accordance with CDC's 1997 guidelines, "Screening Young Children for Lead Poisoning." For HUD-assisted target housing, LSHR defines an "EIBLL" as a confirmed concentration of lead in whole blood ≥ 20 $\mu\text{g}/\text{dL}$ for a single test or ≥ 15 -19 $\mu\text{g}/\text{dL}$ in two tests taken at least 3 months apart.

LSHR also outlines requirements for designated parties (e.g., property owner, public housing agency or other entity with control over operation of the unit). For tenant-based rental assistance, for example, interventions must be targeted to a child <6 years of age identified with an EIBLL who lives in a HUD-assisted dwelling unit within 15 days after being notified by a public health department or other medical healthcare provider. These interventions typically are a risk assessment and interim controls of LBP hazards.

HUD is considering strategies to address CDC's change in policy as a result of the ACCLPP recommendations, such as revising LSHR or modifying program notices. HUD also is exploring the possibility of initiating rulemaking through an assessment of the costs, benefits, burden on small businesses, and feasibility given current resource constraints. Discussions of these issues are underway between the Office of Healthy Homes and Lead Hazard Control and HUD Program Offices. Most notably, the possibility of the RVBL ≥ 5 $\mu\text{g}/\text{dL}$ changing every four years will be particularly challenging for HUD rulemaking.

Recommendation 3. *CDC should help to implement a nationwide primary prevention policy regarding lead hazards.* The HUD Lead Hazard Control Program (LHCP), LSHR and LDR are all primary prevention activities. HUD welcomes the opportunity to continue to collaborate with CDC to identify additional approaches to advance these programs and other primary prevention initiatives.

Recommendation 4. *Clinicians should recommend environmental assessments prior to blood lead screening.* HUD will continue to provide CDC with information on the development and maintenance of lead safe housing and HUD's housing inspection programs for assisted housing to guide the creation of educational materials for clinicians.

Recommendations 5. *Clinicians should monitor the health of children with confirmed BLLs ≥ 5 $\mu\text{g}/\text{dL}$ and provide test results to their families.* HUD addresses follow-up of EIBLL cases in LSHR. For ongoing HUD assistance to target housing, an owner or other designated party who obtains information on an EIBLL case from a source other than a public health department or medical healthcare provider must immediately verify the case with one of these sources. The designated party must control lead hazards if the EIBLL case is verified. HUD is considering the potential impact of the CDC policy change on its current rulemaking.

Recommendation 6. *Clinicians should report BLLs above the reference value to health or housing departments and collaborate with these agencies to ensure that appropriate services and resources are provided.* HUD's existing requirements address follow-up of EIBLL cases. LSHR requires a risk assessment and control of identified lead hazards when information is provided that a child with an EIBLL lives in pre-1978 HUD-assisted housing. HUD is considering the potential impact of the CDC policy change on its current rulemaking.

Recommendation 7. *Stakeholders should be educated on primary prevention of lead exposure in homes and other child-occupied facilities (COFs).* LHCP, LDR and LSHR all require outreach about primary prevention. LSHR specifically contains language regarding COFs in HUD-assisted housing. Lead is one of the focal issues and is deeply embedded in all of HUD's Healthy Homes Programs, including outreach activities on a range of residential primary prevention measures.

Recommendation 8. *CDC should take the following actions: (a) facilitate data sharing, (b) encourage preventive housing standards, (c) identify financing for lead hazard remediation, and (d) provide families with information to protect their children from hazards.* For subpart (a), LSHR requires data sharing between health and housing agencies. For subpart (b), LSHR is

mainly a primary prevention rule that covers HUD-assisted rental and certain owner-occupied target housing. A preexisting rule covers most other owner-occupied target housing.

For subpart (c), the LHCP annual budget of ~\$100 million is the most easily identifiable and largest source of federal funding for lead hazard remediation. Many CLPPPs help property owners complete the HUD application process, identify alternative funding sources and negotiate with local banks. HUD expects the FY2013 LHCP budget to increase to \$120 million.

For subpart (d), LDR requires a warning statement and disclosure before rental or sale. HUD collaborates with both public and private partners to implement various components of its Lead Outreach Program, including the “Lead Free Kids” Campaign and website, fliers and grantee outreach materials. LSHR requires notification before lead hazard control work and after lead hazard evaluation and clearance. The incorporation of the RRP Rule into LSHR allows HUD to enforce EPA rulemaking among state, local and tribal grantees.

Recommendation 9. *CDC should collaborate with elected officials and agencies to ensure adoption of a suite of preventive policies.* In support of primary prevention policies, HUD provides health, housing and code enforcement agencies with technical information and assistance on lead issues in jurisdictions with and without lead hazard control grants.

Recommendation 10. *CDC should emphasize environmental assessments for primary prevention and adopt primary prevention strategies.* HUD has collaborated with CDC, EPA and other partners on implementation of LSHR. Environmental assessments are conducted as a condition of receiving HUD assistance in target housing. HUD, EPA, CDC and other federal agencies are members of the Lead-Based Paint Task Force that serves as forum to develop additional primary prevention strategies.

Recommendation 11. *If a lead hazard that requires a response is found in any unit in a multi-family housing complex, the same response must be applied to all similar untested units in the complex. If a previous risk assessment demonstrated that no lead hazards are present in the other units, however, no retesting is required.*

HUD is aware of technical and economic problems in responding to recommendation 11. Due to considerable inter-unit variability in the presence, extent and location of lead hazards in multi-family housing, extrapolating from one to all units in a complex would waste funds, dilute efforts and overlook other hazards. HUD will carefully consider this issue in its decision-making process on whether to initiate rulemaking on LSHR.

HUD noted that CDC concurred with recommendation 11 in principle and outlined its specific means to address or implement this guidance. CDC agreed with the evidence that a building housing one child with lead poisoning is an indication of the potential risk to other children in the same building. CDC further stated that contingent on funding, recommendations on increased inspections might be implemented in the future. HUD plans to engage CDC in discussions to clarify the wording of the recommendation and reach agreement on the most appropriate interventions to implement.

Recommendations 12 & 13. *CDC should encourage additional research and identify research priorities to develop interventions that are capable of maintaining children's BLLs below the reference value of 5 µg/dL.* HUD includes lead and healthy homes research in its research program (www.hud.gov/lead) and will continue to collaborate with CDC and other federal partners in this effort.

HUD currently is funding several research priorities: spot test kit development, the effect of porches on lead dust inside the home, the impact of soil and dust lead at child care centers on health effects, the ability of robotic floor cleaners to clean up lead, phytoremediation, spatial variability of DLLs on floors, and environmental conditions.

ACCLPP extensively discussed HUD's response to recommendation 11. ACCLPP's guidance stated that if a lead hazard requiring a response was found in any unit in a multi-family housing complex, the same response should be applied to all similar untested units in the complex. Several members were surprised that HUD anticipated additional costs and changes to LSHR rulemaking to implement the recommendation. ACCLPP emphasized that the basic tenet of recommendation 11 was for HUD to focus on multi-family housing complexes with a history of EBLL cases and take necessary steps to prevent another case of childhood lead poisoning in the same building.

Dr. Brown resolved this issue by confirming that she and Dr. Friedman would engage in further dialogue to clarify the overarching intent and purpose of recommendation 11 and report HUD's revised response to ACCLPP.

Agency Response: National Institute for Occupational Safety and Health (NIOSH)

Walter Alarcon, MD, MSc

Project Officer, Adult Blood Lead Epidemiology and Surveillance Program
National Institute for Occupational Safety and Health

Dr. Alarcon presented NIOSH's response to the ACCLPP recommendations. The Occupational Safety and Health Act of 1970 created NIOSH with a mission to provide leadership in research to prevent work-related illness, injury, disability and death. NIOSH's overarching role is to assure safe and healthful working conditions for working men and women through scientific research, guidance and recommendations, dissemination of information, and health hazard evaluations.

NIOSH's workforce of ~1,400 staff has expertise in diverse fields (e.g., epidemiology, medicine, engineering, psychology, chemistry, statistics, economics and administration). In addition to its headquarters in the District of Columbia and Atlanta, NIOSH also maintains facilities in Cincinnati, Morgantown, Pittsburgh, Spokane, Anchorage and Denver. NIOSH's strategic goals focus on four key categories: research through the National Occupational Research Agenda

with an emphasis on high-risk sectors; surveillance; prevention interventions through the Health Hazards Evaluation Program; and information, training and capacity building.

NIOSH collaborates with public and private partners to track occupational injuries, illnesses and fatalities. National databases and state-based surveillance systems are used in this effort (e.g., the Sentinel Event Notification System for Occupational Risk and the Adult Blood Lead Epidemiology and Surveillance (ABLES) Program).

NIOSH has a long history of providing occupational safety and health guidance to ACCLPP and extensively participating in its workgroups: Lead and Pregnancy Workgroup, LOC Workgroup, Laboratory Workgroup, and Consumer Products Workgroup. NIOSH has used ACCLPP's recommendations to respond to requests for occupational advice from partners and other organizations, support the nomination of low-level lead for the National Toxicology Program (NTP) review, and implement interventions on blood lead reference levels.

Examples in which NIOSH has applied ACCLPP's recommendations are summarized as follows. NIOSH used the *CDC Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women* to develop a template of a letter. Healthcare providers use the template to send a letter to employers with their medical opinions regarding occupational lead exposure for specific patients. The purpose of the provider letter is to help prevent work exposures in pregnant and lactating women by informing employers of the impact of lead exposures at work on children and families in the home.

NIOSH used ACCLPP's recommendations to nominate low-level level for NTP review. The review initially was intended to assess the reproductive and developmental effects of lead exposures, but NTP expanded the scope to include cardiovascular, renal, immune and neurological effects in children and adults. The NTP Monograph on Health Effects of Low-Level Lead was published in June 2012.

NIOSH funds 41 states to conduct lead exposure surveillance and prevention for adults through the ABLES Program. ABLES covers a wide spectrum of reference levels for blood lead of workers. For example, the Occupational Safety and Health Administration (OSHA) uses BLLs 50-60 µg/dL for medical removal from work and BLLs 40-49 µg/dL for return to work. The American Conference of Governmental Industrial Hygienists uses BLLs ≥ 30 µg/dL as its Biological Exposure Index. OSHA established BLLs ≥ 25 µg/dL for its National Emphasis Program-Lead in 2008.

NIOSH and its federal and state partners used BLLs ≥ 10 µg/dL as the definition of EBLLs beginning in 2009. ACCLPP and other organizations recommended that BLLs should not exceed 5 µg/dL during pregnancy beginning in 2007. The U.S. geometric mean BLL was ≥ 1.4 µg/dL according to the NHANES Fourth Report.

Dr. Kapil moderated ACCLPP's discussion with Dr. Alarcon on the NIOSH response to the ACCLPP recommendations. The discussion topics included:

- minimal support provided by states to workers identified with EBLLs (e.g., a brochure with no follow-up by providers);
- limited funding from NIOSH to states (e.g., \$10,000-\$33,000 per ABLES grantee annually); and
- efforts to reconcile ACCLPP's upcoming recommendations on laboratory reporting of BLLs ≥ 5 $\mu\text{g/dL}$ and the CDC Nationally Notifiable Condition of BLLs ≥ 10 $\mu\text{g/dL}$.

ACCLPP made two suggestions for NIOSH to consider in its future activities on low-level lead exposure. First, NIOSH should update its website by featuring the template letter from healthcare providers to employers and highlighting specific sections of the "lead in pregnancy" guidelines that address occupational safety and health issues.

Second, NIOSH should compile and present the ACCLPP recommendations on low-level lead exposures, the NTP Monograph on Health Effects of Low-Level Lead and other solid evidence to encourage OSHA to lower its current standard of BLLs 40-60 $\mu\text{g/dL}$ for interventions to adult workers.

Agency Response: Centers for Medicare and Medicaid Services

Cynthia Ruff

Health Insurance Specialist
Centers for Medicare and Medicaid Services
ACCLPP *Ex-Officio* Member

Ms. Ruff presented CMS's response to the ACCLPP recommendations. CMS issued the ACCLPP recommendations to its regional offices with a request to forward the guidance to all state Medicaid agencies. No current CMS policy or statute prohibits states from reimbursing costs for additional services for the new population of children identified with BLLs ≥ 5 $\mu\text{g/dL}$. The Medicaid Early Periodic Screening, Diagnosis and Treatment (EPSDT) Program requires states to provide all medically necessary services to children.

The CMS *State Medicaid Manual* mentions BLLs ≥ 10 $\mu\text{g/dL}$, but states are advised to defer to the expertise of physicians and refer to CDC's recommendations for additional treatment or services to children with EBLLs. CMS has no plans at this time to revise the *State Medicaid Manual* because the current language has sufficient flexibility for states to support the RVBLL ≥ 5 $\mu\text{g/dL}$.

CMS revised the Medicaid policy in June 2012 to allow agencies to target Medicaid-eligible children for blood lead screening. CMS provided states with the policy change, a description of required supporting data, and specific criteria that must be met to shift from universal screening to targeted screening, particularly the development of an evaluation plan.

CMS also convened an all-state call in July 2012 with state Medicaid agencies and health departments. To date, CMS has not received any applications from states to shift from universal screening to targeted screening. As a result, the CMS universal blood lead screening policy for children 1 and 2 years age remains in effect for all states. CMS will solicit expertise from CDC in the review of each targeted screening application.

ACCLPP sent a letter to the CMS Clinical Laboratory Improvement Advisory Committee (CLIAC) in 2010 with guidance on improving lead testing proficiency programs. CLIAC responded that after CDC and CMS complete their significant analysis of data, a proposed rule will be drafted with recommendations to change the current proficiency testing programs, including lead testing. Ms. Ruff will maintain communications with CLIAC to determine a projected timeline when the proposed rule will be drafted.

Dr. Kapil moderated ACCLPP's discussion with Ms. Ruff on the CMS response to the ACCLPP recommendations. The discussion topics included:

- CMS's mechanisms to improve compliance with blood lead screening of Medicaid-eligible children (e.g., funding restrictions, Healthcare Effectiveness Data and Information Set (HEDIS) measures, or Form 416 to report EPSDT performance annually); and
- awards of any CMS Innovation Grants focusing on lead remediation or other healthy homes approaches as cost-saving strategies.

Agency Response: Consumer Product Safety Commission (CPSC)

Kristina Hatlelid, PhD, MPH

Toxicologist, Directorate for Health Sciences
Consumer Product Safety Commission
ACCLPP *Ex-Officio* Member

Dr. Hatlelid presented CPSC's response to the ACCLPP recommendations. CPSC supports the ACCLPP recommendations and the CDC response. CPSC particularly agrees with the development of the RVBLL ≥ 5 $\mu\text{g}/\text{dL}$ as an appropriate approach to interpret BLLs and address lead exposures in children from both scientific and public health perspectives. In light of the large body of information about the adverse health effects of lead and the associated understanding of the exposure-response relationship, CPSC also supports the emphasis on primary prevention.

CPSC statute requires the lead content to be limited to 100 ppm in all parts of products intended for children ≤ 12 years of age with the exception of inaccessible parts and certain electronic devices. However, a new law was passed in 2011 that removed specific children's products

from the CPSC statute (e.g., all-terrain vehicles and similar motor vehicles). Bicycles also have a different lead standard than other children's products.

CPSC implemented a new lead in paint standard that covers all types of consumer paint and several children's products. The new standard was lowered from 600 ppm to 90 ppm. CPSC also phased-in a mandatory product testing standard that covers all health and safety regulations for children's products. Accredited laboratories are required to conduct third-party testing under this standard. Imported products and domestic shipments must be certified and contain tracking labels to aid in future product recalls.

CPSC has deployed staff to Beijing, China to facilitate ongoing coordination and communication with local stakeholders. CPSC has increased its partnership with U.S. Customs and Border Protection to perform surveillance of products at U.S. ports. CPSC developed a new website (www.saferproducts.gov) for the public to more easily report problems with products, obtain information on products that have caused harm, and learn about product recalls.

Dr. Kapil moderated ACCLPP's discussion with Dr. Hatelid on the CPSC response to the ACCLPP recommendations. The discussion topics included:

- the role of XRF testing in the panel of techniques used by laboratories and toy manufacturers to test consumer products for lead; and
- concerns regarding the use of $2 \mu\text{g}/\text{cm}^2$ as an alternative limit for measuring lead in paint in small areas of consumer products.

ACCLPP advised CPSC to explore the possibility of issuing guidance on proper and improper use of XRF for lead testing of children's products beyond the current regulatory language. Dr. Brown confirmed that she would take actions to engage CPSC and EPA in LWG's future discussions to draft recommendations in response to its third charge, "alternate matrices for assessing lead exposure."

Agency Response: National Institute for Environmental Health Sciences

Walter Rogan, MD

Principal Investigator, Pediatric Epidemiology Group
National Institute for Environmental Health Sciences
ACCLPP *Ex-Officio* Member

Dr. Rogan presented NIEHS's response to the ACCLPP recommendations. NIEHS agrees in principle with the ACCLPP recommendation to abandon the LOC for BLLs $\geq 10 \mu\text{g}/\text{dL}$ and place more emphasis on primary prevention. However, NIEHS has no plans at this time to allocate new research dollars to this effort.

NIOSH's nomination of low-level lead resulted in publication of the "NTP Monograph on Health Effects of Low-Level Lead." The monograph serves as an overview of the science to date on potential health effects from low-level lead exposure based on a review of epidemiological data for health effects at BLLs <10 µg/dL. The panel began the review with two basic assumptions. First, health effects from lead are well established at higher levels. Second, CDC's definition of an "elevated blood lead level" is ≥ 10 µg/dL for persons of all ages.

The panel developed four key questions to determine an association between adverse health effects and BLLs <10 µg/dL: (1) What neurological, immune, renal, cardiovascular, reproductive and developmental effects are associated with BLLs <10 µg/dL? (2) What is the BLL (e.g., <10 µg/dL or <5 µg/dL) associated with the health effect? (3) At which life stage (e.g., childhood or adulthood) is the effect identified? (4) Do data exist to evaluate the association between bone lead and the health effect? How does the association to this biomarker of lead exposure compare to the association with blood lead?

The panel's review of the primary literature included epidemiological studies with mean BLLs <10 µg/dL. Study designs and confounders of these studies were carefully considered. Supporting evidence included in the review were bone lead data, laboratory animal data and authoritative sources (e.g., 2006 EPA Air Quality Criteria Document for Lead, 2007 ATSDR Lead ToxProfile™, expertise from technical advisors, and recommendations by an expert peer review).

The panel grouped specific health effects in one of four categories: sufficient evidence of an association, limited evidence of an association, inadequate evidence of an association, or no evidence of an association. For BLLs <10 µg/dL, the panel found sufficient evidence for the following principal health effects: delayed puberty, reduced postnatal growth, decreased IQ, decreased hearing, and increased immunoglobulin E. Limited evidence was found for increased hypersensitivity or allergy to common allergens by skin prick. Inadequate evidence was found for asthma, eczema, non-allergy immune function, cardiovascular effects, and renal function in children <12 years of age.

For BLLs <5 µg/dL, the panel found sufficient evidence for the following principal health effects: decreased academic achievement/specific cognitive measures and increased incidence of ADHD and problem behaviors. Limited evidence was found for delayed puberty, decreased IQ, and decreased kidney function in children ≥ 12 years of age. The monograph now serves as NTP policy on the health effects of low-level lead and is available on the NTP website.

In terms of the lead research portfolio, the NIEHS website describes funding opportunity announcements (FOAs) and grant awards for its Small Business Innovation Research Program and Small Business Technology Transfer Program. NIEHS recently announced grant awards focusing on tools for improved exposure assessment (e.g., remote sensing technologies and wearable technologies) and total-body exposure for persons in the general population.

Dr. Rogan presented a live demonstration of the National Institutes of Health (NIH) Research Portfolio Online Reporting Tools (RePORTER) website. The website provides up-to-date

information on FOAs and research grants for all NIH institutes and centers, including the principal investigators, award amounts and project abstracts. However, NIEHS's substantial lead research portfolio focuses on issues broader than lead. Overall, NIH will make efforts to increase the extramural component of its research grant budget from ~87% to 90%.

ACCLPP extensively discussed approaches for its lead research recommendations to have a more significant impact on the NIEHS grant decision-making process. Dr. Rogan advised ACCLPP to formulate its lead research guidance based on the NIEHS 2012-2017 Strategic Plan (www.niehs.nih.gov/about/strategicplan).

Agency Response: Food and Drug Administration

Benson Silverman, MD

Director, Infant Formula and Medical Foods Staff
Food and Drug Administration
ACCLPP *Ex-Officio* Member

Dr. Silverman joined the meeting via teleconference to present FDA's response to the ACCLPP recommendations. Lead has long been banned from food products, gasoline and soldered cans in the United States, but FDA continues to sporadically address lead contamination in low-profile imported food products. Poor quality manufacturing operations and intentional contamination are the primary causes of lead contamination of food products in the United States.

FDA has an ongoing program to monitor lead contamination in multiple food products (e.g., ceramic ware, candies and dried fruit). FDA issues import alerts if food products are found to violate U.S. lead level regulations. However, FDA does not routinely monitor spices for lead levels due to the potential for low exposure. Lead contamination of spices typically is based on individual rather than commercial importation of these food products into the United States from immigrant populations.

FDA determines whether lead-contaminated food products are legally adulterated. For example, a charge under Section 402(a)(1) means that a food product was adulterated with lead at a level to cause due harm. FDA will continue to collaborate with CDC and state and local health authorities to assess the significance of lead exposure from food products, explain reported elevated lead levels, and identify other potential sources if the lead level was found to be extremely low.

Dr. Silverman concluded his overview by apologizing for being unable to attend his first meeting in person and provide a more detailed response from FDA to the ACCLPP recommendations. He explained that he recently replaced Dr. Michael Bolger as the ACCLPP *ex-officio* member for FDA. As a result, the focus of his first meeting was to become familiar with ACCLPP's overall mission, function and key activities. Dr. Silverman planned to attend the next ACCLPP meeting

in person and provide more substantive information on FDA's activities related to low-level lead exposure in food products.

ACCLPP welcomed Dr. Silverman in his new role as the *ex-officio* member for FDA and looked forward to meeting him in person. During his update at the next meeting, ACCLPP asked Dr. Silverman to specifically respond to the questions and comments set forth below.

- *What will be FDA's response to the U.S. Pharmacopeia (USP) recommendation?* The concentration of lead in pharmaceutical products/supplements has been a longstanding concern, particularly those that are imported from other countries. As a result, the 2010 USP report recommended an acceptable lead level of 10 µg/day for supplements based on FDA's current permissible lead level for bottled water of 5 µg/L. USP asked FDA to endorse its recommendation, but a lead level of 10 µg/day for supplements would be problematic for children.
- *Does FDA plan to change its current "provisional total daily intake for lead?"* The FDA policy is based on CDC's previous LOC BLL ≥ 10 µg/dL rather than the current RVBLL ≥ 5 µg/dL. The Food and Agriculture Organization of the United Nations and other European agencies recently reviewed and supported the elimination of their "provisional tolerable weekly intake for lead" because no known safe level of lead exists.
- *What is FDA's definition of "due harm" (e.g., an EBLL or encephalopathy) from a food product?* FDA bases its definition of health effects from lead on risk assessment findings rather than specific lead levels, but this methodology is unclear.

In the event that FDA is able to respond to ACCLPP's questions and comments before the 2013 meeting, Dr. Brown advised Dr. Silverman to e-mail her the information (mjb5@cdc.gov) for faster distribution to ACCLPP.

Agency Response: U.S. Department of State (DOS)

Kalina Duncan

Foreign Affairs Officer
U.S. Department of State
Alternate ACCLPP *Ex-Officio* Member

Ms. Duncan presented DOS's response to the ACCLPP recommendations on behalf of Ms. Kimberly Coleman, the *ex-officio* member, who was unable to attend the meeting. DOS has no specific response to the ACCLPP recommendations, but lead will continue to be a major issue in DOS's broad EH portfolio.

Several EH priorities have emerged over the past two years with tremendous policy and diplomatic opportunities for DOS. Most notably, DOS has maintained its strong focus on clean cook stoves due to the significant burden of disease from indoor air pollution. DOS also is

continuing to prioritize access to clean drinking water. These two initiatives have allowed DOS to engage global Ministries of Health, Ministries of Environment, U.S. Embassies and technology companies.

The primary role of the DOS Health Policy Office is to ensure that health priorities and issues are considered in environmental policy negotiations and decision-making of both global and domestic partners and organizations. DOS also leverages critical resources of its partners in other countries, solicits diplomatic opportunities and provides a solid context for these activities. For example, DOS serves as a convener of interagency efforts for water and other EH issues.

DOS's ability to maintain a solid and diverse portfolio for lead and other EH issues is based on its strong relationships with federal partners. For example, the "natural" partnership with the U.S. Agency for International Development is broad and focuses on virtually all EH issues. The partnership with CDC historically has focused on water, sanitation and hygiene activities, but opportunities are being explored at this time to expand the DOS/CDC interagency effort to other areas. The partnership with EPA focuses on indoor air pollution and international chemical issues.

The partnership with the Department of Commerce focuses on the development of letters of agreement or memoranda of understanding with countries to address the intersection between health and trade issues. The partnership with NIEHS focuses on climate change and human health issues. The partnership with FDA focuses on imported and exported food safety issues, but to an extremely limited degree. These federal partnerships allow DOS to address lead and other EH issues at a broader scale, including trade and economic implications, health and policy concerns, and diplomatic engagement at the international level.

DOS serves on the International Conference on Chemicals Management and the Strategic Approach to International Chemicals Management to have a voice in these negotiations. DOS hopes to honor its commitment to participate in the WHO Global Alliance to Eliminate Lead Paint. DOS will continue its longstanding efforts to raise the political will of country governments through their Ministries of Health, Ministries of Education, and Ministries of Finance to address lead and other EH issues.

DOS has partnered with embassies as well as environment, health, science and technology officers across the world to encourage countries to participate in "Global Handwashing Day," "World Tuberculosis Day" and other international health events. DOS and its partners attempt to raise awareness and provide education to countries by disseminating data on the burden of disease in their respective communities and the impact on individuals.

DOS utilizes its Embassy Science Fellows Program and International Visitors Leadership Program to maintain a strong focus on the technical exchange of products, prevention, testing and training between U.S. scientists and in-country staff. Overall, DOS welcomes input from federal partners on strategies to increase its presence, value and impact on international EH policy issues.

ACCLPP extensively discussed existing knowledge and data on the burden of lead exposure or EBLs in low-/middle-income countries. For example, WHO currently ranks lead as the 6th public health problem in the global burden of disease. ACCLPP advised DOS to take a leadership role in ensuring that the U.S. government is formally represented on the Global Alliance to Eliminate Lead Paint.

Open ACCLPP Discussion

Dr. Kapil opened the floor for ACCLPP's questions, comments or suggestions on the federal agency responses to the low-level lead recommendations. He also invited the *ex-officio* members to use this session to answer outstanding questions or clarify issues raised during their presentations. The topics covered during the open ACCLPP discussion are outlined below.

- Dr. Brown will review the slope of the curve of previous NHANES data to project potential changes to the RVBL ≥ 5 $\mu\text{g/dL}$ in the future. She will attempt to report her findings to ACCLPP by December 13, 2012.
- EPA has no plans at this time to change the maximum contaminant level for lead in drinking water of 0.015 mg/L. However, the EPA Office of Drinking Water is analyzing water service lines as part of the Lead in Copper Rule and intends to release a proposal for public comment based on ACCLPP's recommendations, new science and data on lower lead levels. Under the Lead Reduction Act, the proposed rule will consider 0.25% as the new level for lead in plumbing and fitting fixtures.

The remainder of the open discussion was devoted to ACCLPP's comments regarding communication of the RVBL ≥ 5 $\mu\text{g/dL}$. Most notably, the members pointed out that ACCLPP has not clarified or reached consensus on language to clearly describe elevated or undue lead exposure at BLLs ≥ 5 $\mu\text{g/dL}$ for public health, laboratories or clinical settings.

ACCLPP further noted that the current terminology includes "elevated blood lead level," "environmental intervention blood lead level," "lead-poisoning," "lead toxicity," and "reference value." The members emphasized that the use of multiple terms in CDC/ACCLPP guidance will be extremely confusing to state and local health agencies, clinicians, parents, educators and other stakeholders.

ACCLPP proposed two options in an effort to resolve this issue. For option 1, CDC should continue to fund and support the LOC Workgroup because the full extent of its original charge was not met. For option 2, CDC should allow workgroup members to contribute their individual time and expertise on an ad hoc basis to formulate communication strategies and implementation plans for the RVBL ≥ 5 $\mu\text{g/dL}$. The workgroup members would then present their findings to the full ACCLPP membership.

Dr. Brown made several comments and clarifying remarks in response to ACCLPP's discussion. ACCLPP originally charged the LOC Workgroup with two major tasks: (1) compile solid data to support lowering the CDC LOC for BLLs ≥ 10 $\mu\text{g/dL}$ and (2) explore communication strategies if ACCLPP recommends a change to CDC policy. Since that time, CDC no longer has resources to reconvene the original workgroup or support the formation of a new workgroup to address part 2 of the charge.

In response to option 1, Dr. Brown confirmed that CDC is continuing to explore approaches internally to ensure clear and consistent messaging of the RVBLL ≥ 5 $\mu\text{g/dL}$ is developed and widely disseminated to diverse stakeholders.

In response to option 2, Dr. Brown explained that FAC charters prohibit individual members from meeting informally and reporting to the parent committee. However, she planned to consult with MASO to discuss any potential exceptions to the rules for FAC members to meet. She also raised the possibility of ACCLPP's ongoing workgroups taking responsibility for proposing communication strategies and implementation plans for the RVBLL ≥ 5 $\mu\text{g/dL}$.

Public Comment Session

Carolyn Grossman

Communications and Public Affairs Consultant
Magellan Biosciences/Mirepoix

Ms. Grossman made the following comments for ACCLPP's consideration. At this time, ~8 states have implemented pay-for-performance measures associated with lead testing. These measures have made a tremendous difference in increased lead testing by both Medicaid health plans and providers. As an incentive, for example, Wisconsin awards \$1 million bonuses to health plans that raise their lead testing rates by 10%. As a punitive measure, Maryland retains a portion of funds from health plans that do not reach lead testing goals for their pediatric populations.

In terms of CMS Innovation Grant Awards, a senator wrote a letter to the Acting CMS Administrator emphasizing the need to reduce preterm births and improve birth outcomes for both mothers and their children. The letter further advised CMS to act favorably on programs that propose LPP activities during the process of evaluating Innovation Grant applications.

In terms of LPP education, Connecticut convened an educational forum that resulted in the state health and education departments jointly developing guidelines for school districts on the prevention and management of lead poisoning in children. The guidelines included prevention recommendations, guidance on recognizing and identifying children early, and suggestions on lead exposure educational programming to help mitigate existing or potential deficits. Efforts also are underway in Connecticut to align the ACCLPP recommendations on low-level lead exposure to automatic eligibility for early intervention services for children 0-3 years of age.

Ms. Grossman advised ACCLPP to recommend broad replication of the Connecticut models at the national level. The joint effort by the state health and education departments in providing LPP education to the educational community has been extremely successful.

Reva Berman

Policy and Program Advisor
Health Canada

Ms. Berman joined the meeting by teleconference to ask whether FDA plans to suspend the tolerable daily intake for lead. She also thanked CDC for allowing members of the public to participate in ACCLPP meetings via teleconference. Dr. Silverman confirmed that he would consult with his colleagues at FDA to respond to Ms. Berman's question.

With no further discussion or business brought before ACCLPP, Dr. Kapil recessed the meeting at 4:31 p.m. on November 15, 2012.

Opening Session: November 16, 2012

Christopher Portier, PhD

Director, CDC National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry
Acting ACCLPP Chair and Designated Federal Official

Dr. Portier announced that he and Dr. Cibulas would serve as the Acting Chair and DFO for the ACCLPP meeting in the absence of Dr. Kapil. He opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. He confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 16, 2012. Dr. Portier reconvened the proceedings at 9:18 a.m. and welcomed the participants to day 3 of the meeting.

Update on U.S. Department of Housing and Urban Development Activities

Warren Friedman, PhD, CIH

Senior Advisor, Office of Healthy Homes and Lead Hazard Control
U.S. Department of Housing and Urban Development
ACCLPP *Ex-Officio* Member

Dr. Friedman presented an update on three of HUD's major activities that are underway.

HUD Guidelines. The *Second Edition of the HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing* (www.hud.gov/offices/lead/lbp/hudguidelines) was published in September 2012. The entire 800-page book or individual chapters, appendices and slides can be downloaded for training or other purposes. A crosswalk between steps in lead hazard control projects and the guidelines is described. Additional materials will be developed and posted on the HUD website in the future (e.g., a booklet of all forms, frequently asked questions and an e-book). The 1995 edition of the guidelines will remain on the website as a reference for HUD grantees.

HUD collaborated with several internal and external partners in publishing the guidelines, including the National Center for Healthy Housing, ICF International, Atrium Environmental Health and Safety Services, and Sagetopia. Contributions by these partners included drafting the first iteration of the guidelines, providing editorial support, conducting internal and external reviews, and designing the layout.

Key changes between the 1995 and 2012 guidelines are summarized as follows. Regulations and policies implemented by HUD, EPA, CPSC, OSHA and the U.S. National Park Service (NPS) are described. CDC's guidance on EBLs is a key feature. Knowledge gained from field and laboratory experiences and advances in technology are highlighted. Advice given by HUD and other experts to housing owners, funding agencies and lead professionals is outlined.

Chapter 3, "Before You Begin: Planning to Control Lead Hazards," describes the EPA Abatement Rule and RRP Rule for certified firms, supervisors, inspectors, risk assessors and renovators. Aspects of the HUD LSHR are summarized (e.g., required evaluation and control activities for federally-owned and federally-assisted housing). A high-level summary is provided that compares the HUD LSHR and the EPA RRP Rule.

Chapter 11, "Interim Controls," describes the LSHR, Pre-Renovation Education (PRE) Rule, RRP Rule, and OSHA Lead in Construction Standard. Step-by-step guidance on interim controls is provided. The following HUD policy is reiterated: "Clearance is highly recommended even when not required by regulation." The role and benefits of these regulations are emphasized.

Chapter 16, "Investigation and Treatment of Dwellings that House Children with Elevated Blood Lead Levels," includes a new summary of recommendations, new list of recommended actions, and new descriptions of "assessment" and "remediation." The chapter covers the ACCLPP recommendations on low-level lead exposure, CDC's response to the guidance, and other evidence that has been gathered since publication of the 1995 guidelines. Because decisions on HUD rulemaking are pending, the existing EIBLL thresholds and approaches are maintained to ensure continuity of guidance to state and local agencies.

Chapter 18, "Lead-Based Paint and Historic Preservation," updates the NPS guidance and invokes the RRP Rule, LSHR and OSHA Lead in Construction Standard. Caution on chemical stripping is emphasized to avoid glue melting. Several recommendations are made to protect the historicity of the home. Most notably, no caustic strippers should be used that can raise

wood grain unless a trained specialist supervises this renovation. No power sanding should be used that can abrade wood surfaces. No hot-tank dipping should be used that might loosen glued joints.

The updated and expanded glossary includes new terms in plain language, simplified regulatory definitions for the sake of clarity, and clearer definitions to address concerns raised by users of the guidelines. Many appendices and references are updated and link to websites of federal agencies.

Appendix 5.1, “Structured On-the-Job Training (OJT) versus Unstructured OJT,” includes a discussion and references for structured OJT; an analysis of jobs categorized into component tasks; lesson plans and materials for instructors; a description of consistent and cost-effective measures; an overview of criteria to complete OJT for LBP activities (e.g., the RRP Rule); and the rationale for HUD’s recommendations on structured OJT.

Appendix 6, “Lead Paint Rules,” provides overviews and guidance materials on regulations: EPA-HUD LDR, HUD LSHR, EPA RRP, EPA PRE Rule, and EPA Training and Certification Rule; OSHA lead regulations for general industry, construction and hazard communication; CPSC bans on lead in paint and lead in consumer products used by children; and NPS rules and guidance on protection of historic properties. The chapter also describes differences and interactions between the HUD LSHR and the EPA RRP Rule.

Appendix 9, “Lead-Based Paint Liability Insurance,” describes professional liability coverage for LBP evaluation, contractor’s pollution liability coverage for lead hazard control, claims-made and occurrence coverage, policy limits regarding aggregates and deductibles, and recommended minimum characteristics of insuring entities.

Lead Standards Review. EPA received a petition from several professional societies in August 2009 (e.g., National Center for Healthy Housing, Alliance for Healthy Homes and Sierra Club) to lower the regulatory lead dust standard and modify the regulatory definition of “lead-based paint.” EPA took two major actions in response to the petition. First, EPA established a regulatory docket and posted a notice and other documents on the Federal eRulemaking Portal (www.regulations.gov) in October 2009. Second, EPA contacted HUD to initiate an interagency effort in analyzing data and other issues.

In its formal response to the petition, EPA confirmed its collaboration with HUD. The HUD Secretary has statutory authority to establish a lower level of lead in paint for purposes of LBP in target housing, while the EPA Administrator identifies LBP hazard standards for target housing and COFs as well as LBP in COFs.

In the summer of 2012, HUD issued a *Federal Register* notice announcing its plans to collect information from 100 lead hazard control grantees to support the study to lower lead hazard standards and the LBP standard. The survey design focuses on two key areas: (1) the ability of HUD grantees to achieve “clearance” (i.e., a work area that is sufficiently clean of lead dust) at the current level for floors and windowsills before allowing reoccupancy and (2) the technical

feasibility to achieve clearance at potentially lower levels. The survey will include questions on both grantee and housing characteristics, cleaning procedures, clearance results, and the frequency of and responses to initial clearance failures.

No public comments were submitted in response to HUD's *Federal Register* notice by the August 21, 2012 deadline. HUD issued a Notice of Submission of Proposed Information Collection to the Office of Management and Budget in October 2012 and stated that EPA and HUD intended to have identical standards for the sake of maximizing their effectiveness.

Spot Test Kit Development and Research. HUD awarded a CoAg in FY2011 to develop and conduct validation testing of sodium sulfide test kits with various compositions. A sodium sulfide kit that is similar to ESCA Tech's D-Lead Kit[®] and was evaluated by the EPA Environmental Testing Verification (ETV) Program was tested as a control. To achieve full recognition under the RRP Rule, EPA requires spot test kits to yield a false-positive rate of $\leq 10\%$ at $< 0.8 \text{ mg/cm}^2$ and a false-negative rate of $\leq 5\%$ at $> 1.2 \text{ mg/cm}^2$.

The ETV results for the D-Lead Spot Test Kit were false-positive rates of 16% and 29% based on one technical operator and one non-technical operator and a false-negative rate of 0%. Because the D-Lead Kit failed the false-positive rate and passed the false-negative rate (associated with its having a 50% response point of $\sim 0.6 \pm 0.1 \text{ mg/cm}^2$), full recognition under the EPA RRP Rule could not be achieved.

The rationale for HUD's ongoing research is to develop new spot test kits with a 50% response point near 1.0 mg/cm^2 and steep performance curves to meet RRP criteria. To adjust the 50% response point, several method parameters covering the amount of samples collected and diluted were varied in a predetermined manner. Tests on a range of kits were conducted by two operators who used 44 National Institute of Standards and Technology (NIST) sample panels that EPA previously used to perform test kit evaluations in support of the RRP Rule.

Preliminary research results show that two separate test kits achieved an acceptable false-positive rate of $\leq 10\%$ and an acceptable false-negative rate of $\leq 5\%$ by both operators. After the test results are further analyzed and reported to EPA, a peer-reviewed paper will be submitted for publication.

Dr. Portier moderated ACCLPP's discussion with Dr. Friedman on HUD's ongoing activities. The discussion topics included:

- HUD's plans to revisit the existing EIBLL rule to be consistent with CDC's new policy for EBLLs; update the 2012 guidelines accordingly (e.g., Chapter 16 and supporting references); and provide ACCLPP with regular status reports on the HUD rulemaking process;
- LSHR definitions of "tenant-based rental assistance" (e.g., housing choice voucher) versus "HUD-assisted housing;"

- HUD's studies on the length of time clearance can be sustained at lower levels over time; and
- the statistical and methodological reliability and stability of testing if the lead level in paint is lowered.

In follow-up to the discussion, Dr. Friedman invited ACCLPP to make a presentation to HUD on the rationale to adopt the RV BLL ≥ 5 $\mu\text{g}/\text{dL}$ to inform decisions on the rulemaking process. The presentation would allow HUD to obtain expert input from diverse sources.

ACCLPP commended HUD on its enormous efforts to update and publish the 2012 guidelines on LBP in housing. The members pointed out that the state-of-the-art guidelines are extremely valuable in the field and serve as the gold standard to train inspectors, abatement contractors and other groups. ACCLPP further noted that the guidelines provide useful recommendations for renovations to private housing.

ACCLPP made two suggestions for HUD to consider in its ongoing research and other activities. First, HUD plans to engage statisticians in revising the current concentration of lead in paint (e.g., 5,000 ppm) that is considered "lead-based." However, HUD also should obtain expertise from other important disciplines in this effort, particularly toxicology and analytical chemistry.

Second, "real-world" standard reference materials should be included in the development, evaluation and validation of new spot test kits at various lead concentrations. NIST samples are homogenous, stable and traceable and are better than those actually used in the field.

Update on International Childhood Lead Poisoning Prevention Efforts

Mary Jean Brown, ScD

Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Brown presented an update on international childhood LPP efforts that are being conducted by CDC and its domestic and global partners. CDC and its partners are continuing to focus on the critical issue of lead poisoning from artisanal gold-ore processing in Zamfara, Nigeria. CDC recently completed its third investigation in Zamfara to support a population-based study with a cluster design.

CDC initiated the study by providing an intensive one-week training course to residents in the Field, Epidemiology and Laboratory Training Program in May 2012. CDC obtained a representative sample of villages in Zamfara to achieve three major objectives of the study: (1) provide unbiased prevalence estimates of villages engaged in artisanal mining; (2) provide unbiased prevalence estimates of children's BLLs in mining and non-mining villages; and (3)

estimate the distribution of BLLs of all in children ≤ 5 years of age living in Zamfara and stratify BLLs by village mining status.

CDC and its partners in the field also are conducting two complementary and parallel studies. Study 1 is focusing on sickle cell disease and trait status of children ≤ 5 years of age. Study 2 is focusing on lead levels in open and closed drinking water wells in mining and non-mining areas of Zamfara. Traditional and religious leaders in the villages have been extremely supportive of CDC conducting the studies.

To date, CDC and EPA have collected 840 venous blood lead samples on children ≤ 5 years of age, 840 sweep/dust samples, 166 water samples and 50 electrets. CDC also administered 840 in-depth questionnaires on the ages, habits and other characteristics of children. The 2012 Dooyema, *et al.* study reported that 71% of family compounds in two villages participated in ≥ 1 ore processing activities in June 2010: rock breaking, rock grinding, rock washing, rock drying, rock separating or rock melting. Family compounds participated in four activities on average.

The 2012 Lo, *et al.* study reported that 77% of 70 villages continued to participate in gold-ore processing activities during the previous 12 months, but most activities were conducted outside of family compounds. The most recent investigation showed that 58% of villages continue to participate in ore processing, but 17% continue to break rocks in villages and only 6% continue to grind ore in villages. CDC's health education campaign and strong support by religious leaders were the contributing factors to changing behaviors in the villages.

An analysis of the distribution of water sources by village showed that the top four sources are open wells, closed wells (bore holes/pumps), streams/rivers and ponds. Closed wells have no lead levels; open wells have lead at levels that are higher than U.S. permissible limits; and streams/rivers and ponds are highly contaminated with lead. These water sources serve wildlife in addition to humans, but lead contamination of food sources has not been quantified to date. No evidence was found of unusually high infant/child mortality in the villages, but children in Bagega continue to be identified with severe symptoms. A few deaths have been reported in this community as well.

In May 2012, Dr. Brown and two ACCLPP members (Mr. Perry Gottesfeld and Dr. Michael Kosnett) attended the "International Conference on Lead Poisoning with a Special Focus on the Zamfara Crisis" in Abuja, Nigeria. The conference led to the adoption of 7 recommendations:

1. immediately approve and release urgent funding;
2. prioritize remediation of Bagega;
3. institutionalize a response to the prevention of contamination and safe mining;
4. establish regulatory frameworks and assure their effective functioning;
5. prioritize an institutional response to health;
6. streamline community involvement and engagement throughout all activities; and
7. ensure interdisciplinary coordination of the response.

Several developments occurred following the May 2012 conference. Funds were released, but are being reviewed by the Secretary to the Federation of Nigeria. Suggestions were made that a biologic remediation might be more “scientific.” Human Rights Watch and Médecins Sans Frontières have taken leadership to increase international pressure on the release of funds and cleanup through excavation. Overall, emergency funding that the U.S. Ambassador to Nigeria allocated to address lead poisoning from artisanal gold-ore processing has been depleted, but CDC plans to remain engaged and continue to provide support from Atlanta.

The Strategic Approach to International Chemical Management/International Conference on Chemical Management (ICCM) passed a resolution in 2010 to eliminate residential use of lead paint internationally by 2020. IPEN and other international organizations found that residential lead paint is for sale in >20 countries with developing economies. Small-scale manufacturers produce some lead paint, but U.S. paint companies and other large-scale manufacturers also are producers of lead paint.

To achieve this goal, the Global Alliance to Eliminate Lead Paint (GAELP) was established and formally charged with eliminating the use of lead in decorative paints worldwide by 2010. WHO and the United Nations Environment Programme jointly support GAELP with primary funding from EPA and additional donations from Norway, Thailand and other countries. The GAELP Interim Advisory Committee and subgroups focus on five key areas: human health, environmental protection, liaison with industry, worker health and legislation, and regulation. Dr. Brown and Mr. Gottesfeld co-chair two of the GAELP subgroups.

The GAELP framework is organized into three categories. The “information” component is used to identify areas and populations at highest risk, lead paint sources and alternatives. The “action” component is used to mobilize targeted and coordinated efforts at local, national and global levels. The “awareness” component is used to share relevant information with key stakeholders.

The ICCM resolution encourages all governments, civil society organizations and private industry in all regions to contribute to GAELP’s efforts and provide technical and financial assistance whenever possible for the following activities. Awareness should be raised on the toxicity of lead paint on human health and the environment. Knowledge of alternatives should be increased. Data gaps on lead paint should be filled, particularly exposure pathways for vulnerable populations (e.g., children <6 years of age, paint users and workers).

Guidance and assistance should be provided to identify potential lead exposures. Capacity should be built to conduct blood lead testing, perform surveillance, and assess residential and occupational risks from lead paint. Public and professional education programs should be implemented on the mitigation of lead poisoning. International third-party certification of new paint products should be promoted to help consumers recognize paint and coatings without added lead.

Prevention programs should be implemented to reduce exposure, particularly in and around housing, childcare facilities, schools and other buildings where lead paint has been used in the

past as well as in industrial facilities that produce or use paint with added lead compounds. National regulatory frameworks should be promoted to stop the manufacture, import, sale and use of lead paints and products coated with lead paints. Companies should be encouraged to substitute lead compounds added to paint with safer alternatives.

The ICCM resolution also expresses support for GAELP's proposal to establish an "International Lead Poisoning Prevention Day of Action" that initially will focus on the elimination of lead in paints. The first LPP day of action will be held in October 2013, but without formal international recognition from the United Nations. However, materials produced by U.S. agencies and organizations will be provided to countries with an interest in participating.

Several steps will be taken in preparation of developing a proposal for formal U.N. recognition of an International Lead Poisoning Prevention Day of Action in 2014. An inventory will be created of materials that are used in national awareness campaigns in different countries. Countries with an interest in learning more about national LPP days of action and collaborating in these efforts will be identified. A virtual workgroup will be established to discuss and share materials and guidance.

Efforts are underway to address ~55 million tons of mine tailings and metallurgical waste from eight sites in Kosovo. Estimates show that the sites contain 12% of zinc, 3% of lead, 250 grams/ton of silver, and 250 grams/ton of gold. A Fulbright scholar was awarded a fellowship to collaborate with CDC and other experts in the United States and Canada to develop a business plan and submit a proposal to the U.S. Agency for International Development, World Bank and other groups. The proposal will outline a plan to entirely replace rather than refurbish the Trepca smelter and fund the upgrade with proceeds from processing mine tailings.

Mr. Gottesfeld presented a brief update on international childhood LPP activities by his organization, Occupational Knowledge Institute (OKI). OKI partnered with the Ministry of Mines in Nigeria to examine gold-ore processing areas outside of Zamfara State. Lead contamination from gold-ore was detected in another region, but no efforts have been made to date to follow-up on these findings.

OKI produced a report in 2011 that described the export of used lead batteries to Mexico and compared differences between standards and performance of the recycling industry in the United States and Mexico. The OKI report resulted in a front-page article in *The New York Times* and a thorough investigation by the Commission for Environmental Cooperation (CEC) on trans-boundary shipment of used lead batteries and recycling practices in Mexico and other countries.

CEC held a meeting in October 2012 in Mexico City to discuss its preliminary findings. The final report is expected to be released by the end of 2012 with recommendations on regulations and oversight of the recycling industry in Mexico. The report also will have implications for U.S. practices in safely exporting used lead batteries to Mexico and ~20 developing countries.

Mr. Gottesfeld concluded his update by reiterating the importance of Dr. Brown's leadership in addressing lead poisoning in Nigeria and other parts of the world. He emphasized that CDC's public health expertise in LPP efforts is unique and cannot be filled by any other agency in the world.

ACCLPP Business Session

The business session was opened for ACCLPP's review, discussion or formal action on the following topics.

Topic 1: Adoption of the Draft ACCLPP Meeting Minutes

A motion was entertained for ACCLPP to approve the minutes of the January 4, 2012 teleconference meeting. A motion was properly placed on the floor and seconded by Dr. Deborah Cory-Slechta and Mr. Dana Williams, respectively, for ACCLPP to approve the minutes. **ACCLPP unanimously adopted the Draft Minutes of the January 4, 2012 Teleconference Meeting with no changes.**

Dr. Ezatollah Keyvan-Larijani is the ACCLPP liaison representative for the Council of State and Territorial Epidemiologists. He noted that during the public comment session of the January 4, 2012 teleconference meeting, Dr. Cynthia Driscoll expressed strong concerns regarding ACCLPP's use of pooled analysis data and conclusions by Dr. Bruce Lanphear in recommending the elimination of BLLs ≥ 10 $\mu\text{g/dL}$ as the CDC LOC. Dr. Keyvan-Larijani questioned whether this issue was addressed.

Dr. Brown explained that CDC provided a response to Dr. Driscoll's comments, but Dr. Lanphear was not contacted in this matter. She confirmed that CDC's response would be circulated to ACCLPP for review.

The Draft Minutes of the November 14-16, 2011 ACCLPP Meeting were distributed for review and would be formally adopted during a future teleconference or the next face-to-face meeting.

Topic 2: Future Action Items

Dr. Brown reviewed the action items that were raised over the course of the meeting.

- Dr. Brown and Mr. Jeffrey Jarrett will use the slide set that Dr. Patrick Parsons presented on day 1 of the meeting to develop interim guidelines and a narrative to assist LWG in addressing the remainder of its charge over the next few weeks. LWG will focus on a uniform RVBLL for adults in this effort.

- Drs. Brown and Sher Lynn Gardner will coordinate ACCLPP's comments on the draft educational intervention report and develop the next version of the document early in 2013 for review and discussion during the next EIWG teleconference.

Topic 3: Changes to the ACCLPP Membership

Dr. Brown presented plaques to two ACCLPP members whose terms have expired: Drs. Brenda Reyes and Kimberly Hansen, *in absentia*. The participants joined Dr. Brown in applauding the tremendous service and commitment of Drs. Reyes and Hansen to ACCLPP and CDC as well as their outstanding contributions to the broader childhood LPP community.

Dr. Reyes thanked CDC for providing her with an extremely enjoyable and educational opportunity to serve as an ACCLPP member over the past four years. During her tenure, she was impressed by the high level of expertise and knowledge of her fellow ACCLPP members.

Dr. Reyes explained that in her position as the Chief of the Community and Children's Environmental Health Bureau for the City of Houston Health and Human Services, ACCLPP and CDC have provided her with valuable expertise, guidance and support to resolve problems in the field. She asked Dr. Brown to continue to communicate via e-mail to keep her informed of ACCLPP's activities.

Topic 4: Draft ACCLPP Letter to the HHS Secretary and CDC Director

Dr. Michael Kosnett presented the draft letter to the HHS Secretary and CDC Director on the RVBLL ≥ 5 $\mu\text{g}/\text{dL}$ for ACCLPP's review. The members extensively discussed the letter and proposed several revisions to strengthen or clarify the text.

At the conclusion of the discussion, a motion was properly placed on the floor and seconded by Dr. Megan Sandel and Mr. Dana Williams, respectively, for ACCLPP to accept the revisions and approve the following version of the letter for submission to the HHS Secretary and CDC Director.

Dear Secretary Sebelius and Director Frieden:

As members of the CDC Advisory Committee on Childhood Lead Poisoning Prevention, we are charged with offering advice and guidance on scientific aspects of lead toxicity, and recommendations regarding improvements in national childhood lead poisoning prevention efforts. Earlier this year, our Committee issued a report that highlighted the adverse neurodevelopmental effects of lead at very low levels and recommended public health actions to investigate and respond to childhood blood lead concentrations that exceed a "reference value," currently corresponding to 5 $\mu\text{g}/\text{dL}$. It is estimated that approximately 500,000 children in the United States have blood lead concentrations that meet or exceed this value. Because lead exposure disproportionately impacts minority

and low-income children, it represents a substantial contributor to health disparities and environmental justice concerns.

Years of experience have demonstrated the efficacy of CDC's Lead Poisoning Prevention Program in reducing and mitigating childhood lead exposure in communities across the country. The essential elements of CDC's federal program and the state and local programs it supports have included expert guidance and technical assistance in (a) surveillance, identification and case management of children with harmful exposure to lead; (b) inspection and remediation of the sources of elevated exposure; (c) improvements in the quality of laboratory measurements of lead; and (d) education of the public and healthcare providers on the importance of primary prevention. CDC's Lead Poisoning Prevention Program analyses have been instrumental in guiding the actions of other federal entities, such as HUD and EPA.

A well-established principle of public health practice holds that in the allocation of limited resources, precedence should be given to programs and interventions that offer the greatest return on human and financial investment. Judged by this metric, CDC's Lead Poisoning Prevention Programs have demonstrated unparalleled efficacy in the field of public health. Based on the findings of recent peer-reviewed cost-benefit analyses [REF], CDC estimates that between 2008 and 2010, the efforts of its national and state-supported programs to reduce lead exposure and its negative neurodevelopmental impacts in 3 million children yielded savings of \$26 to \$57 billion in lifetime productivity earnings alone. Additional savings associated with decrements in lead-related behavioral disorders, juvenile delinquency, and the need for special education would increase this substantial benefit.

Unfortunately, the recent change in available resources diverges in an opposite direction from recent scientific advances demonstrating the health impact of very low lead exposures and has the potential to widen existing health disparities. In light of this and in response to recent programmatic cutbacks, our Committee urges prompt action to restore and maintain the full scope of CDC's national and state-supported Lead Poisoning Prevention Programs.

ACCLPP unanimously approved the motion with no further changes.

Dr. Brown confirmed that she would provide the reference for "recent peer-reviewed cost-benefit analyses" to aid in finalizing the letter. She also would circulate the final letter to the entire ACCLPP membership.

Topic 5: Lead Exposure from Secondhand Smoke

Dr. Warren Friedman submitted the following paragraph for inclusion in the formal ACCLPP record. The text was provided by Dr. Peter Ashley, Director of the Policy and Standards Division, HUD Office of Healthy Homes and Lead Hazard Control.

HUD sponsored the collection of lead dust samples from the homes of young children participating in NHANES (1999-2004). Analyses of these data suggest that lead from secondhand smoke was a significant contributor to lead in house dust and children's blood in this general population sample. The presence of a smoker in the home was a significant predictor of dust-lead loadings on both floor and windowsill samples in multivariate models.¹ The presence of a smoker in the home and serum cotinine concentration were significant predictors of children's blood-lead levels in a multivariate model.² These findings are consistent with a previous analysis of earlier NHANES data that reported serum cotinine to be a significant predictor of elevated blood lead (≥ 10 $\mu\text{g/dL}$) in children 4-16 years of age.³

¹Gaitens, JM *et al.* (2009). *Environ Health Perspect.* 117:461-467.

²Dixon, SL *et al.* (2009). *Environ Health Perspect.* 117:468-474.

³Mannino, DM *et al.* (2003). *Epidemiology.* 14:719-727.

Public Comment Session

Dr. Cibulas opened the floor for public comments; no participants responded.

Closing Session

Dr. Cibulas thanked the ACCLPP members for their tremendous energy, expertise and passion to help CDC in strengthening its childhood LPP portfolio. He was particularly impressed by the thoughtful and insightful guidance ACCLPP provided to CDC, ATSDR and their federal partners over the course of the meeting.

The participants joined Dr. Cibulas in applauding Ms. Sandra Malcom (NCEH/ATSDR BSC Executive Coordinator) and Ms. Shirley Little for their outstanding efforts in overseeing the logistics, making travel arrangements and performing the necessary administrative functions for the ACCLPP meeting.

With no further discussion or business brought before ACCLPP, Dr. Cibulas adjourned the meeting at 11:52 a.m. on October 16, 2012.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Vikas ("Vik") Kapil, DO, MPH, FACPOEM
Acting Chair & Designated Federal Official
Advisory Committee on Childhood Lead
Poisoning Prevention